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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GOODNOW

Serial No: 09/616,283

Filed: July 14, 2000

For: SYSTEM FOR DETECTING BACTERIA IN BLOOD, BLOOD PRODUCTS, AND FLUIDS OF TISSUES

Art Unit: 1645

Attorney Docket No. VRXB-P01-001

Examiner: J. Hines

Assistant Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration Under 37 C.F.R. §1.132

Sir:

I, Harvey G. Klein, MD., hereby declare as follows:

1. I am the Chief of the Department of Transfusion Medicine at the Warren C. Magnuson Clinical Center, National Institutes of Health. I have been working and conducting research in the field of transfusion medicine for over thirty (30) years. I serve on the Food and Drug Administration's (FDA) Blood Products Advisory Committee. I actively hold leadership positions in the American Association of Blood Banks, the American Blood Commission, the American Society of Hematology, and the American Society of Apheresis. I currently serve as Chairman of the Committee of Revision for Blood and Blood Products for the U.S. Pharmacopeia. I am a diplomat of the American Board of Internal Medicine and a diplomat of the American Board of Pathology. I have authored and co-

more than 175 publications on transfusion medicine. Accordingly, my curriculum vitae is attached as Appendix A.

2. I have read the above-identified application, the pending claims, and the Office Action mailed on September 29, 2003.

3. I understand that the Examiner has stated that the invention as described and claimed in the above-identified application is obvious in view of the teachings of Fisher et al. WO 98/57994, McLaughlin (U.S. Patent 4,683,196), Tadler et al. (*J. Clin. Lab. Anal.* 3: 21-25 (1989)), Erich et al. (*J. Immunol.* 143(12): 4053-4060, 1989), and Chang et al. (U.S. Patent 5,200,323).

4. For the reasons stated below, I respectfully disagree with the Examiner. I have been working in the field of transfusion medicine for over thirty (30) years and over the past two decades the issue of bacterial contamination has been a source of primary concern for blood collectors and transfusion service scientists and clinicians. It is estimated that as many as one in 12,000 transfusions lead to a severe septic reaction and as many as one in 46,000 transfusions can lead to death due to bacterial contamination. In the recent years, it has been further reported that an unexpectedly large number of deaths were attributed to bacterial contamination/sepsis. For example, the fatality rate for transfusion related bacterial sepsis during the period from 1999 to 2002 averaged more than 15%.[1]

(a) [1] People's Choice Award - 2003 FDA Science Forum; "Transfusion Related Fatalities from Bacterial Contamination of Blood Components," L.E.Simmons, MT(ASCP)[1], M.A.Knippen[2], L.G.Holness, M.D.[3], [1]OCBQ, CBER, FDA, Rockville, MD, [2]OCBQ, CBER, FDA, Rockville, MD, [3]OBRR, CBER, FDA, Rockville, MD

Although, blood banks routinely test each unit of donated blood for human immunodeficiency virus (HIV), hepatitis B and C virus, syphilis, and Human T-cell Lymphotrophic Virus (HTLV) and discard units which have abnormal test results, they do not test for bacterial contamination because of the lack of a safe and effective test.[2] Accordingly, the nation's leading blood safety experts have been repeatedly calling for immediate action from the blood banking community to initiate a program to detect the presence of bacteria in blood and blood products.

5. As early as 1992, P. Ann Hoppe[3] reported that that although numerous studies had been performed by the FDA and others, no rapid and reliable tests existed that could be readily applied in the blood bank setting. See Transfusion 1992; 32(3): 199-201.

6. In December 1997, a multi-center study for the systematic collection of data concerning bacterial contamination of blood components (BaCon Study) was initiated under the guidance of the American Association of Blood Banks (AABB), the American Red Cross (ARB), and the Center for Disease Control and prevention (CDC). The goals of this study included determining the rates of bacterial contamination associated with recipient transfusion reactions, identification of responsible micro-organisms, and identification of risk factors for bacterial contamination.

7. On February 23, 1999, Jane Henney, the FDA commissioner testified as follows before the U.S. House of Representatives in a hearing on issues of blood safety: "The safety and

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[2]American Red Cross web site on safety of donated blood: www.givelife2.org/donor/bloodsafety.asp. See Appendix B

[3] The Acting Director, Division of Transfusion Science of the FDA.

adequacy of the blood supply and blood products is one of the highest priorities of the FDA and the Department of Health and Human Resources. . . For a number of serious and life-threatening infections, there is a limited period after a possible donor has been infected, which the infection is not detectable by available methods. ... The risk to patients from bacterial contamination of blood and from blood band error must also be reduced."

8. Despite this long felt need and high level of interest in the field for a rapid and effective screening assay to detect clinically relevant amounts of bacteria in blood and blood products, to the best of my knowledge no such reliable test is currently on the market. In fact, due to the lack of such reliable testing methods, the Food and Drug Administration (FDA) guidelines require shorter storage times as a means for controlling the increase in bacterial contamination upon storage. However, the trade-off is reduced blood availability.

9. I list below certain tests that have been developed over the past two decades in an effort to alleviate this problem. However, none of these have proven to be effective in detecting clinically relevant amounts of bacteria.

- RNA probes were developed as universal probes to detect bacterial contamination; however, this method was too cumbersome for routine blood bank screening and was associated with a high rate of contamination. These probes are no longer being marketed by the manufacturer.

- Visual inspections also did not prove to be a useful method for detecting bacterial contamination.

- Testing for glucose levels was not found to be a viable alternative because certain contaminants like *S. epidermis*, a common skin contaminant, grows slowly and glucose changes could not be detected until later in the storage period.

- Filtration methods had no impact on the bacterial levels – in no case were the bacteria eliminated, and in fact, bacteria reached the same titer at the stationary phase of growth, whether or not the pool was filtered.

- Certain antigen detection systems using latex agglutination, fluorescent antibody stains, and enzyme-linked immunosorbent, are available, however, these methods have been plagued with variable sensitivity and specificity. As taught in the Verax application, an obvious concern with regards to detection of blood contaminants is the requirement of a ubiquitous microbial antigen to ensure detection of diverse bacterial species.

- Around the mid-1990s, the American Red Cross, in collaboration with a commercial company Binax, developed a prototype assay using immunological methods to detect bacterial contamination of blood components. The test was developed to detect the presence of a common microbial antigen, peptidoglycan, by immunochromatography. However, Binax subsequently abandoned the test due to its inability to detect all the bacteria implicated in platelet transfusions as peptidoglycans are not expressed on the surface of Gram negative bacteria.

10. Therefore, to date, despite the repeated call for improved testing methodologies, and despite the numerous attempts to develop effective tests, there is no effective method for detecting bacterial contamination. I believe that the Verax test provides a non-obvious solution to meet this long-felt need in the blood banking arena.

11. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

Dated: 12/1/2003

Signature: Harvey G. Klein

Dr. Harvey G. Klein
Chief, Department of Transfusion Medicine
Warren C. Magnuson Clinical Center
National Institutes of Health

CURRICULUM VITAE

HARVEY G. KLEIN, M.D.

DATE OF BIRTH: May 8, 1943

PLACE OF BIRTH: Boston, Massachusetts

MARITAL STATUS: Married, June 20, 1965

WIFE'S NAME: Sigrid Petri

CHILDREN: Susanna Rebecca, born July 26, 1969
Stephan Eliot, born February 3, 1972
Melissa Kathryn, born June 30, 1976

HOME ADDRESS: 13628 Canal Vista Court, Potomac, MD 20854

OFFICE ADDRESS: National Institutes of Health
Warren G. Magnuson Clinical Center
Department of Transfusion Medicine
10 Center Drive, Building 10, Room 1C711
Bethesda, MD 20892-1184

EDUCATION:

1955-1961	Boston Latin School (Franklin Medalist)
1961-1965	Harvard College, A.B. (magna cum laude)
1965-1969	The Johns Hopkins School of Medicine, M.D.

POSTGRADUATE TRAINING:

1969-1970	Internship, The Johns Hopkins Hospital Department of Medicine
1970-1972	Resident, The Johns Hopkins Hospital, Department of Medicine
1972-1973	Fellow in Hematology, The Johns Hopkins Hospital, Department of Medicine

MILITARY SERVICE:

1973-1975	Commissioned Corps, Public Health Service

PROFESSIONAL APPOINTMENTS:

Present:	Chief, Department of Transfusion Medicine
1997-present	Executive Committee, Warren G. Magnuson Clinical Center
1990-94	Special Assistant to the Director for Science, Warren G. Magnuson Clinical Center, NIH
1983	Tenured Scientist
1976-83	Assistant Chief, Blood Bank Department, NIH
1976-83	Chief, Blood Services Section, Clinical Center Blood Bank, NIH
1975-6	Acting Chief of Blood Services, Clinical Center Blood Bank, NIH
1974-5	Chief, Hemorrhagic Diseases Program, Division of Blood Diseases, NHLBI, NIH
1973-5	Assistant to the Director, Division of Blood Diseases and Resources, NHLBI, NIH

CERTIFICATION:

Maryland Medical License, 1969 (#K87ll)
Diplomate, American Board of Internal Medicine, 1972 (#39283)
Diplomate, Hematology Subspecialty - ABIM, 1976 (#39283)
Diplomate, American Board of Pathology, Blood Bank Specialty, 1977

ACADEMIC APPOINTMENT:

1995-present Johns Hopkins School of Medicine – Visiting Professor, Pathology
1990-present Johns Hopkins School of Medicine – Visiting Professor, Medicine

PROFESSIONAL SOCIETIES:

American Federation of Medical Research
American Society of Hematology
American Association of Blood Banks
American Society for Apheresis
International Society of Blood Transfusion

AWARDS AND HONORS:

Detur Award (Harvard)
Phi Beta Kappa
Award of Distinction, American Society of Medical Writers, 1975
Commendation Medal, Public Health Service, 1980

Peacock Lecturer, University of Texas (Dallas), 1984
Equal Opportunity Achievement Award, Public Health Service, 1985
Elmer L. DeGowin Lectureship, University of Iowa, 1986
Meritorious Service Medal, Public Health Service, 1989
PHS Unit Commendation, 1991
Clarence Schein Memorial Lectureship, Montefiore Medicine Center, New York, 1991
Visiting Professor, Mayo Clinic Section of Transfusion Medicine, 1991
NIH Clinical Center Director's Award, 1992
John B. Alsever Award (contributions to the blood banking sciences), 1993
Annual Lecture Award - American Society for Apheresis and 5th World Apheresis Association Congress, 1994
Charles E. Walter Memorial Award, Mid Atlantic Association of Blood Banks, 1995
Allen Latham Award (European Society for Haemapheresis), 1995
Tibor J. Greenwalt Lectureship, 1996
Cohn DeLaval Medal (World Apheresis Association), 1996
Joseph R. Bove Visiting Professorship, Yale, 1997
Rita and Taft Schreiber Memorial Lectureship Cedars-Sinai Medical Center, 1998
Corresponding Membership, German Blood Transfusion Society, 1998
Distinguished Visiting Professor of Pathology, The Johns Hopkins School of Medicine, 1999
Visiting Professor of Pathology, University of Pennsylvania, 1999
Chairman, 24th International Symposium of Blood Transfusion, The Netherlands, 1999
HHS Secretary's Distinguished Services Award, 2000
NIH Director's Award, 2000
Millennial Medical Festival Lecturer, Royal College of Physicians, London, 2000
Distinguished Lecturer, Texas Blood Institute, San Antonio, 2000
Emily Cooley Award (American Association of Blood Banks) 2001
Francis Morrison Memorial Lecture (American Society for Apheresis) 2003
Keynote Speaker, Paul Ehrlich Institute (Frankfurt) 2003

CONSULTANT APPOINTMENT:

Attending Physician, Clinical Hematology Branch, NHLBI, 1975-96
FAES Graduate School at NIH (Immunohematology), 1976-1986
National Heart, Lung and Blood Institute, Division of Extramural Affairs, 1977-present
National Blood Resources Education Program (NBREP) 1988-91
Uniformed Services University of Health Science, Clinical Asst. Prof., 1977-present
Letterman Army Institute of Research, Blood Peer Review Panel, 1987-92
Erythropoietin Advisory Board - Ortho Biotech Corp., 1989-95
Haemonetics Corp. Scientific Advisory Board

AIBS - Medical Free-electron Laser Program, 1990-91
Somatogen Corp., Advisory Board (recombinant human hemoglobin), 1989-98
American Medical Association - Drug Evaluations Annual, 1992
Cryopharm - Scientific Advisory Board (lyophilized blood cells), 1994-5
Zymequest - Scientific Advisory Board (universal red cells), 1994-present
AMA Therapeutic Technology Assessment
Office of Naval Research – Navy-Army Blood Program, 1998-2000
British Blood Authority, 1998 - present
Alliance Pharmaceuticals (perfluorocarbon oxygen carriers), 1998-Present
New Jersey Department of Health & Senior Services (Bloodless Surgery) 1999
Sangart (hemoglobin-based oxygen carriers), 1999-Present
World Health Organization, 2000
Viacell Medical Scientific Advisory Board (cell expansion) 2000 – Present
Vitex Scientific Advisory Board (pathogen reduction of blood) 2001-Present
Gambro BCT Medical Advisory Board (pathogen reduction of blood) 2001
Johns Hopkins Hospital Advanced Transfusion Practices Center, 2000 – 2002

EDITORIAL BOARD MEMBERSHIP:

Editor-in-Chief, Journal of Clinical Apheresis, 1986-94
Transfusion, 1994-present
Transfusion Medicine Reviews, 1994-present
Blood, 1988 - 1993
Infusion Therapy and Transfusion Medicine (German Society of Blood Transf.)
NIH Alumni Update (Founding Member), 1989 - 1996

PROFESSIONAL ACTIVITIES:

American Association of Blood Banks

President, 2000-2001
President – elect, 1999-2000
Vice President, 1997-1999
Board of Directors, 1995-2002
Chairman, Board of Trustees, Research Foundation, 1985-9
Co-chairman, Scientific Strategic Plan, 1989
Transfusion Practices Committee, 1982-8
Therapeutic Hemapheresis Committee, 1983-6
Nominations Committee, 1990, 1992, 2003
Ad Hoc Standards Committee for Marrow Processing Facilities, 1991
Strategic Planning Committee, 1991-3,
Standards Committee, 1991-6, Chairman , 1993-6
North America Task Force for Stem Cell Standards, 1994-6
Board of Directors, National Blood Data Resource Center, 2002-3

American Blood Commission

Board of Directors, 1985-8, ASFA representative

American National Red Cross

Blood Services Advisory Committee, 1981-3
Committee for Protection of Human Subjects, 1983-7
Scientific Council for Biomedical Research , 1985-9
Chairman, Transfusion Science Initial Review Group, 1985-9
Board of Directors, Washington Region , 1989-94
Chairman, Medical Advisory Committee, Blood Services Washington Region, 1988-92
Blood Services Committee, Washington Region, 1988-90
Blood Services Committee, Greater Chesapeake and Potomac Region, 1990
Board of Directors, Chesapeake and Potomac Blood Program, 1992 - present

American Society of Hematology

Scientific Subcommittee in Clinical Laboratory Hematology, 1991-97
Transfusion Medicine Subcommittee, 1993-8
Chairman, Transfusion Medicine Education Program, 1997, 1998
International Outreach Initiative – Subcommittee for Asia

American Society for Apheresis

President, 1985
Board of Directors, 1981-7
Chairman, Clinical Applications Committee, 1983-7
Chairman, Scientific Program, 1984, 1990

FDA

Blood Products Advisory Committee, 2002 - present
Advisory Panel on Orphan Drugs
Blood donors at risk for AIDS - subject matter expert
Workshop on Criteria for Evaluation of Red Cell Substitutes, 1999
Workshop on Leukoreduction of Blood Components, 1999

Haemonetics Corporation

Medical Advisory Board, 1988-99

Board of Directors, 1998-2002

Institute of Medicine

Blood Safety Forum, 1994-95
Committee on Resuscitation Fluids, 1998

International Society of Blood Transfusion

Scientific Committee – Int'l Congress (2000) Vienna
BEST Working Party, 1999-present
Scientific Committee International Congress (2004 Edinburgh

Metropolitan Washington Blood Banks, Inc.

Board of Directors, 1979-82
Chairman, Committee on Regionalization, 1979-80

National Marrow Donor Program (NMDP)

President, NMDP Council, 1993-4
Board of Directors, 1992-95
Membership Committee, 1988-92
Research and Publications Committee, 1990-95
International Affairs Committee, 1990-92
Vice President for Donor Centers, NMDP Council, 1992-94

National Heart, Lung and Blood Institute

National Blood Resources Education Program
Chairman, Data Safety and Monitoring Committee,
TRAP Study, 1991-6
Chairman, Data Safety & Monitoring Committee, T-Cell
Depletion Trial, 1994-2002

National Institute on Aging

Clinical Research Subpanel, 1982-5

National Institute of Allergy and Infectious Diseases

Expert Panel on the Effects of Donor Pool Size on the Safety and Efficacy of Immunoglobulin Products, 1998

U.S. Public Health Service

Advisory Committee on Blood Safety and Availability,2001- present
PHS Executive Task Force on AIDS, Charlottesville,VA, 1988
Medical Review Board, 1982-96
USPHS Working Group on HTLV-I, 1988
Medical Board, Clinical Center, NIH, 1982-4, 1989-91
NIH Strategic Planning Committee (Molecular Medicine Initiative Subcommittee), 1992
Secretary's Committee on Clinical Center Options, 1995

U.S. Pharmacopeia

Committee of Revision, Chairman: Blood and Blood Products, 1995-2000
Committee of Experts – Chairman, Blood & Blood Product Standards, 2000-2005

World Apheresis Association

Board of Directors, 1993-5
Councillor - North America, 1986-88, 1992-4
Scientific Program Committee, 1984, 1986, 1992, 1994

World Health Organization

Consultant to Global Blood Program - 2001

Invited lecturer (including plenary or keynote lectures) at numerous national and international meetings.

Ad hoc reviewer for numerous scientific and medical journals.

BIBLIOGRAPHY:

PEER REVIEWED JOURNALS:

Klein HG, Bell W. Disseminated Intravascular Coagulation Occurring During Heparin Therapy. Ann Int Med 1974; 80-477-481.

Klein HG, Aledort LM, Bouma BN., et al. A Cooperative Study for the Detection of the Carrier State of Classic Hemophilia. N Engl J Med 1977; 296:959-962.

Klein HG. A Chimpanzee Breeding Colony for Hepatitis Research: J Med Primat 1978; 7:182-184.

Weiss GB, Nienhuis AW, McIntosh CL, Klein HG. Traumatic Cardiac Hemolytic Anemia as a Late complication of a Starr-Edwards Mital Valve Prosthesis. Arch Intern Med 1979; 139:373-375.

Klein HG, Faltz LA, McIntosh CL, Appelbaum F, Deisseroth AB, Holland PV. Surgical Hypothermia in a Patient with a Cold Agglutinin: Management by Plasma Exchange. Transfusion 1980; 20:354-357.

Miller DM, Winslow RM, Klein HG, Wilson KC, Statham NJ, Brown FL, Fulmer J. Improved Exercise Performance after Exchange Transfusion in Subjects with Sickle Cell Anemia. Blood 1980;56:1127-32.

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Kolins J, Allgood JW, Burghardt D, Klein HG, McGinniss MH. Modification of B, I, i, and Lewis Antigens in a patient with DiGuglielmo's erythroleukemia. Transfusion 1980; 20:574-77.

Diamond WJ, Brown F, Bitterman P, Klein HG, Davey R, Winslow RM. Delayed Hemolytic Transfusion Reaction Presenting as Sickle Cell Crisis. Ann Int Med 1980; 93-231-34.

Coles SM, Klein HG, Holland PV. Alloimmunization in two multi-transfused patient populations: Sickle Cell Disease and Thalassemia Major. Transfusion 1981; 21:462-67.

Corash L, Klein HG, Deisseroth A, Shafer B, Rosen S, Beaman J, Griffith P, Nienhuis A. Selective Isolation of Young Erythrocytes for Transfusion Support of Thalassemia Major Patients. Blood 1981; 57-599-606.

Gadek JE, Klein HG, Holland PV, Crystal RG. Replacement Therapy of Alpha l-antitrypsin Deficiency: Reversal of Protease-Imbalance within the Alveolar Structures of Piz Subjects. J Clin Invest 1981; 68-1158-65.

Kessler CV, Klein HG, Havlik RJ. Uncontrolled Thrombocythemia in Chronic Myeloproliferative Disorders. Brit J Haem 1982; 50(1):157-67.

Klein HG, Kessler C, Anderson KC, Loomis KF. Multiple Arterial and Venous Thromboemboli in a Male with Chronic Myelogenous Leukemia and Occult Metastatic Breast Carcinoma. South Med J. 1982; 75:745-747.

Lenes B, Klein HG, Lakatos E. Selective Removal of Sickle Cells with the IBM 2997 Continuous Flow Blood Cell Separator. J. Clin. Apheresis 1983; 1:64-70.

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Lane HC, Masur H, Longo DL, Klein HG, Rook AH, Quinnan GV, Steis RG, Macher A, Whalen G, Edgar LC, Fauci AS. Partial Immune Reconstitution in a Patient with the Acquired Immunodeficiency Syndrome. N Engl J Med 1984; 311: 1099-1109.

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Grindon AJ, Tomasulo PA, Bergin JJ, Klein HG, Miller JD, Mintz PD. The Hospital Transfusion Committee: Guidelines for Improving Services. JAMA 1985; 253:540-543.

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Klein HG, Balow JE, Dau PC, Hamburger MI, Leitman SF, Pineda AA, and Tindal RSA: Clinical Application of Therapeutic Apheresis. J Clin Apheresis 1986; 3(7):1-93.

AuBuchon JP, Carter CS, Adde MA, Meyer DR, Klein HG. Optimization of Parameters for Maximization of Plateletpheresis and Lymphocytapheresis yields on the Haemonetics Model V50. J. Clin. Apheresis 1986; 3(2):103-110.

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Muul LM, Nason-Burchenal K, Carter CS, Cullis H, Slavin D, Hyatt C, Director EP, Leitman SF, Klein HG, Rosenberg SA. Development of an automated closed system for generation of human lymphokine activated killer (LAK) cells for use in adoptive immunotherapy. J Immunol Methods 1987; 101:171-181.

Carter CS, Leitman SF, Cullis H, Muul LM, Nason - Burchenal K, Rosenberg SA, Klein HG. Use of a continuous flow cell separator in density gradient isolation of lymphocytes. Transfusion 1987; 27:362-365.

Areman EM, Simonis T, Carter C, Read EJ, Klein HG. Bulk cryopreservation of lymphocytes in glycerol. Transfusion 1988; 28:151-156.

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Kruskall MS, Mintz PD, Bergin JJ, Johnston MFM, Klein HG, Miller JD, Rutman R, Silberstein L. Transfusion therapy in emergency medicine. Ann Emergency Med 1988; 17:327-335.

Sloand EM, Kessler CM, McIntosh CL, Klein HG. Neutralization of heparin-induced anticoagulation with methylene blue. Thromb. Res. 1989, 54:677-86.

Carter CS, Leitman SF, Cullis H, Muul LM, Nason-Burchenal K, Rosenberg SA, Klein HG. Technical Aspects of lymphokine-activated killer cell production. J. Clin. Apheresis 1988; 2/3:113-117.

Leitman SF, Klein HG, Melpolder JJ, Shih JW, Read EJ, Harvarth L, Darr F, Foy JL, Alter HJ. Clinical implications of positive tests for antibodies to human immunodeficiency virus type 1 in asymptomatic blood donors. N Engl of Med 1989; 321:917-23.

Sloand EM, Fox SM, Banks SM, Klein HG. Preparation of IgA deficient platelets. Transfusion 1990; 30:322-326.

Loiacono B, Carter G, Leitman S, Klein HG. Efficacy of various methods of confidential unit exclusion in identifying potentially infectious blood donations. Transfusion 1989; 29:823-6.

DePalma L, Palmer R, Leitman SF, Dolan WD, Klein HG. Utilization patterns of frozen autologous red blood cells: experience in a referral center and a community hospital. Arch Pathol Lab Med 1990; 114:516-18.

Bergsten P, Amitai G, Kehrl J, Dhariwal KR, Klein HG, Levine M. Millimolar concentrations of ascorbic acid in purified human mononuclear leukocytes: depletion and reaccumulation. J Biol Chem 1990; 265:2584-2587.

Sloand EM, Klein HG. Effect of white cells on platelets during storage. Transfusion 1990; 30:333-338.

Lane HC, Zunich KM, Wilson W, Cefali F, Easter M, Kovacs JA, Masur H, Leitman SF, Klein HG, Steis RG, Longo DL, Fauci AS. Syngeneic bone marrow transplantation and adoptive transfer of peripheral blood lymphocytes combined with zidovudine in human immunodeficiency virus infection. Ann Int Med 1990; 113:512-19.

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Fricke W, Alling D, Kimball J, Griffith P, Klein H. Lack of efficacy of tranexamic acid in thrombocytopenic bleeding. Transfusion 1991; 31:345-348.

Keilholz U, Klein HG, Korbling M, Brado B, Carter CS, Cullis H, Galin F, Hunstein W. Peripheral blood mononuclear cells collection from patients undergoing adoptive immunotherapy or peripheral blood-derived stem cell transplantation and from normal donors. J. Clin Apheresis 1991; 6:131-6.

Sloand EM, Klein HG, Pastakia KP, Pierce P, Prodouz KN. Effects of albumin on the inhibition of platelet aggregation by beta lactam antibiotics. Blood 1992; 79:2022-27.

Sloand EM, Klein HG, Banks SM, Vareldzis B, Merritt S, Pierce P. Epidemiology of thrombocytopenia in HIV infection. Eur J. Haem 1992; 48:168-172.

Natanson C, Hoffman WD, Koev LA, Dolan DP, Banks SM, Bacher J, Danner RL, Klein HG, Parrillo JE. Plasma exchange does not improve survival in a canine model of human septic shock. Transfusion 1993; 33:243-8.

Stroncek DF, Holland PV, Bartsch G, Bixby T, Simmons RG, Antin JH, Anderson KC, ASH PC, Bolwell BH, Hansen JH, Heal JM, Henslee-Downey PJ, Jaffe' ER, Klein HG, Lau PM, Perkins HA, Popovsky MA, Price TH, Rowley SD, Stehling LC, Weiden PL, Wissel ME, McCullough J. Experiences of the first 493 unrelated marrow donors in the National Marrow Donor Program. Blood 1993; 81:1940-46.

Sloand E, Kumar P, Klein HG, Merritt S, Sacher R. Transfusion of blood products in HIV-1 infected persons: relationship to opportunistic infection. Transfusion 1994; 34:48-53.

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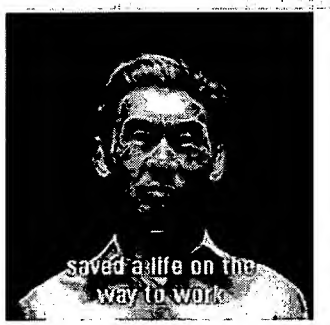

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Donor Safety
Donating blood is a safe and easy process.

- It is not possible to get AIDS or other infectious disease by giving blood.
  A sterile, disposable needle is used for each blood donation. Once used, the needle is discarded.
- Feeling faint or fatigued after donating blood is rare or minor.
  If it occurs, it most likely will pass in a matter of hours.
- You can only donate if your health history permits and you feel well.
  You are asked some health questions and are given a mini physical — temperature, pulse, blood pressure, and red cell count check - prior to donation to ensure that you are feeling well and that it is safe for you to give blood.
- Your health history and test results are confidential and cannot be given out without your permission, except as required by law.
- You can help ensure your experience is a positive and rewarding one:
  Stay in the canteen area for the requested period of time; mention to the staff any unusual feelings or sensations; and avoid strenuous exercise or heavy lifting for about 5 hours after donating.

Blood Safety
Assuring the safety of the blood supply is a high-tech process requiring rigorous testing, proper processing, labeling, and storage, and careful quality control. To help ensure that the blood is as safe as possible, the American Red Cross:

- Accepts donations only from voluntary blood donors
- Provides information about high-risk behaviors associated with transmissible diseases that may impact one's ability to donate blood
- Conducts a behavioral and health history interview and a mini physical exam with all donors prior to donation
- Provides a confidential opportunity for donors to ask that their blood be discarded

- Provides a confidential 800-number donors can call with any questions or concerns post donation
- Tests every donation* for infectious diseases, including HIV, hepatitis B and C virus, syphilis, and other infectious diseases, and discards units which have abnormal test results
- Invests in research and technology to support the development of new and more sophisticated tests

Tests performed on each unit of donated blood*

Disease	Test	Year Implemented
HIV/ AIDS	HIV/AIDS HIV- I Antibody test	1985
	HIV-1/2 Antibody test	1992
	HIV-I p24 Antigen test	1996
HIV/AIDS and Hepatitis C	Nucleic Acid Test (NAT) **	1999
Hepatitis C	Hepatitis C Anti-HCV	1990
Hepatitis B	Hepatitis B Surface Antigen test	1971
	Hepatitis B Core Antibody	1987
Hepatitis	Hepatitis ALT	1986
Syphilis	Syphilis Serologic test	1948
Human T-cell Lymphotropic Virus (HTLV)	HTLV-I Antibody	1989
	HTLV -I/II Antibody	1998

* Not all tests are performed on autologous donations (blood a recipient donates for him or herself). If an autologous donation is not used by the donor, it is discarded.

**A West Nile Virus test will be added to this list in 2003 under an investigational license.

NOTE: This list is subject to change as new blood safety opportunities and requirements emerge. Additional tests may be performed to meet special patient needs.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GOODNOW

Serial No: 09/616,283

Filed: July 14, 2000

For: SYSTEM FOR DETECTING BACTERIA IN BLOOD, BLOOD PRODUCTS, AND FLUIDS OF TISSUES

Art Unit: 1645

Attorney Docket No. VRXB-P01-001

Examiner: J. Hines

Assistant Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration Under 37 C.F.R. §1.132

Sir:

I, Harvey G. Klein, MD., hereby declare as follows:

1. I am the Chief of the Department of Transfusion Medicine at the Warren C. Magnuson Clinical Center, National Institutes of Health. I have been working and conducting research in the field of transfusion medicine for over thirty (30) years. I serve on the Food and Drug Administration's (FDA) Blood Products Advisory Committee. I actively hold leadership positions in the American Association of Blood Banks, the American Blood Commission, the American Society of Hematology, and the American Society of Apheresis. I currently serve as Chairman of the Committee of Revision for Blood and Blood Products for the U.S. Pharmacopeia. I am a diplomat of the American Board of Internal Medicine and a diplomat of the American Board of Pathology. I have authored and co-

authored more than 175 publications on transfusion medicine. Accordingly, my curriculum vitae is attached as Appendix A.

2. I have read the above-identified application, the pending claims, and the Office Action mailed on September 29, 2003. I have been asked by Verax Biomedical, Inc. to comment upon the meaning of the term "donor" to a person of skill in this area.

3. In the blood banking discipline, the term "donor" is a universally recognized term of art. Federal Law mandates that only healthy and asymptomatic subjects are allowed to donate blood. Prior to donating, each individual must undergo a thorough screening process that includes temperature, pulse, blood pressure, hemoglobin content in the blood, and questions about general health, background and travel. See AABB Association Bulletin #99-10, dated December 2, 1999, attached herewith as Appendix B. See also the blood donation eligibility guidelines as set forth by the American Red Cross, herewith attached as Appendix C. If the donor fails any of these questions/requirements, the individual is turned away from the donation center to prevent provision of adulterated components to blood recipients. Thus, in the blood banking arena the term "donor" means a healthy or asymptomatic subject qualified to donate blood.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both,

under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

Dated: 12/1/2003

Signature: Harvey G. Klein

Dr. Harvey G. Klein
Chief, Department of Transfusion Medicine
Warren C. Magnuson Clinical Center
National Institutes of Health

CURRICULUM VITAE

HARVEY G. KLEIN, M.D.

DATE OF BIRTH: May 8, 1943

PLACE OF BIRTH: Boston, Massachusetts

MARITAL STATUS: Married, June 20, 1965

WIFE'S NAME: Sigrid Petri

CHILDREN: Susanna Rebecca, born July 26, 1969
Stephan Eliot, born February 3, 1972
Melissa Kathryn, born June 30, 1976

HOME ADDRESS: 13628 Canal Vista Court, Potomac, MD 20854

OFFICE ADDRESS: National Institutes of Health
Warren G. Magnuson Clinical Center
Department of Transfusion Medicine
10 Center Drive, Building 10, Room 1C711
Bethesda, MD 20892-1184

EDUCATION:

1955-1961	Boston Latin School (Franklin Medalist)
1961-1965	Harvard College, A.B. (magna cum laude)
1965-1969	The Johns Hopkins School of Medicine, M.D.

POSTGRADUATE TRAINING:

1969-1970	Internship, The Johns Hopkins Hospital Department of Medicine
1970-1972	Resident, The Johns Hopkins Hospital, Department of Medicine
1972-1973	Fellow in Hematology, The Johns Hopkins Hospital, Department of Medicine

MILITARY SERVICE:

1973-1975	Commissioned Corps, Public Health Service

PROFESSIONAL APPOINTMENTS:

Present:	Chief, Department of Transfusion Medicine
1997-present	Executive Committee, Warren G. Magnuson Clinical Center
1990-94	Special Assistant to the Director for Science, Warren G. Magnuson Clinical Center, NIH
1983	Tenured Scientist
1976-83	Assistant Chief, Blood Bank Department, NIH
1976-83	Chief, Blood Services Section, Clinical Center Blood Bank, NIH
1975-6	Acting Chief of Blood Services, Clinical Center Blood Bank, NIH
1974-5	Chief, Hemorrhagic Diseases Program, Division of Blood Diseases, NHLBI, NIH
1973-5	Assistant to the Director, Division of Blood Diseases and Resources, NHLBI, NIH

CERTIFICATION:

Maryland Medical License, 1969 (#K8711)
Diplomate, American Board of Internal Medicine, 1972 (#39283)
Diplomate, Hematology Subspecialty - ABIM, 1976 (#39283)
Diplomate, American Board of Pathology, Blood Bank Specialty, 1977

ACADEMIC APPOINTMENT:

1995-present Johns Hopkins School of Medicine – Visiting Professor, Pathology
1990-present Johns Hopkins School of Medicine – Visiting Professor, Medicine

PROFESSIONAL SOCIETIES:

American Federation of Medical Research
American Society of Hematology
American Association of Blood Banks
American Society for Apheresis
International Society of Blood Transfusion

AWARDS AND HONORS:

Detur Award (Harvard)
Phi Beta Kappa
Award of Distinction, American Society of Medical Writers, 1975
Commendation Medal, Public Health Service, 1980

Peacock Lecturer, University of Texas (Dallas), 1984
Equal Opportunity Achievement Award, Public Health Service, 1985
Elmer L. DeGowin Lectureship, University of Iowa, 1986
Meritorious Service Medal, Public Health Service, 1989
PHS Unit Commendation, 1991
Clarence Schein Memorial Lectureship, Montefiore Medicine Center, New York, 1991
Visiting Professor, Mayo Clinic Section of Transfusion Medicine, 1991
NIH Clinical Center Director's Award, 1992
John B. Alsever Award (contributions to the blood banking sciences), 1993
Annual Lecture Award - American Society for Apheresis and 5th World Apheresis Association Congress, 1994
Charles E. Walter Memorial Award, Mid Atlantic Association of Blood Banks, 1995
Allen Latham Award (European Society for Haemapheresis), 1995
Tibor J. Greenwalt Lectureship, 1996
Cohn DeLaval Medal (World Apheresis Association), 1996
Joseph R. Bove Visiting Professorship, Yale, 1997
Rita and Taft Schreiber Memorial Lectureship Cedars-Sinai Medical Center, 1998
Corresponding Membership, German Blood Transfusion Society, 1998
Distinguished Visiting Professor of Pathology, The Johns Hopkins School of Medicine, 1999
Visiting Professor of Pathology, University of Pennsylvania, 1999
Chairman, 24th International Symposium of Blood Transfusion, The Netherlands, 1999
HHS Secretary's Distinguished Services Award, 2000
NIH Director's Award, 2000
Millennial Medical Festival Lecturer, Royal College of Physicians, London, 2000
Distinguished Lecturer, Texas Blood Institute, San Antonio, 2000
Emily Cooley Award (American Association of Blood Banks) 2001
Francis Morrison Memorial Lecture (American Society for Apheresis) 2003
Keynote Speaker, Paul Ehrlich Institute (Frankfurt) 2003

CONSULTANT APPOINTMENT:

Attending Physician, Clinical Hematology Branch, NHLBI, 1975-96
FAES Graduate School at NIH (Immunohematology), 1976-1986
National Heart, Lung and Blood Institute, Division of Extramural Affairs, 1977-present
National Blood Resources Education Program (NBREP) 1988-91
Uniformed Services University of Health Science, Clinical Asst. Prof., 1977-present
Letterman Army Institute of Research, Blood Peer Review Panel, 1987-92
Erythropoietin Advisory Board - Ortho Biotech Corp., 1989-95
Haemonetics Corp. Scientific Advisory Board

AIBS - Medical Free-electron Laser Program, 1990-91
Somatogen Corp., Advisory Board (recombinant human hemoglobin), 1989-98
American Medical Association - Drug Evaluations Annual, 1992
Cryopharm - Scientific Advisory Board (lyophilized blood cells), 1994-5
Zymequest - Scientific Advisory Board (universal red cells), 1994-present
AMA Therapeutic Technology Assessment
Office of Naval Research – Navy-Army Blood Program, 1998-2000
British Blood Authority, 1998 - present
Alliance Pharmaceuticals (perfluorocarbon oxygen carriers), 1998-Present
New Jersey Department of Health & Senior Services (Bloodless Surgery) 1999
Sangart (hemoglobin-based oxygen carriers), 1999-Present
World Health Organization, 2000
Viacell Medical Scientific Advisory Board (cell expansion) 2000 – Present
Vitex Scientific Advisory Board (pathogen reduction of blood) 2001-Present
Gambro BCT Medical Advisory Board (pathogen reduction of blood) 2001
Johns Hopkins Hospital Advanced Transfusion Practices Center, 2000 – 2002

EDITORIAL BOARD MEMBERSHIP:

Editor-in-Chief, Journal of Clinical Apheresis, 1986-94
Transfusion, 1994-present
Transfusion Medicine Reviews, 1994-present
Blood, 1988 - 1993
Infusion Therapy and Transfusion Medicine (German Society of Blood Transf.)
NIH Alumni Update (Founding Member), 1989 - 1996

PROFESSIONAL ACTIVITIES:

American Association of Blood Banks

President, 2000-2001
President – elect, 1999-2000
Vice President, 1997-1999
Board of Directors, 1995-2002
Chairman, Board of Trustees, Research Foundation, 1985-9
Co-chairman, Scientific Strategic Plan, 1989
Transfusion Practices Committee, 1982-8
Therapeutic Hemapheresis Committee, 1983-6
Nominations Committee, 1990, 1992, 2003
Ad Hoc Standards Committee for Marrow Processing Facilities, 1991
Strategic Planning Committee, 1991-3,
Standards Committee, 1991-6, Chairman , 1993-6
North America Task Force for Stem Cell Standards, 1994-6
Board of Directors, National Blood Data Resource Center, 2002-3

American Blood Commission

Board of Directors, 1985-8, ASFA representative

American National Red Cross

Blood Services Advisory Committee, 1981-3
Committee for Protection of Human Subjects, 1983-7
Scientific Council for Biomedical Research , 1985-9
Chairman, Transfusion Science Initial Review Group, 1985-9
Board of Directors, Washington Region , 1989-94
Chairman, Medical Advisory Committee, Blood Services Washington Region, 1988-92
Blood Services Committee, Washington Region, 1988-90
Blood Services Committee, Greater Chesapeake and Potomac Region, 1990
Board of Directors, Chesapeake and Potomac Blood Program, 1992 - present

American Society of Hematology

Scientific Subcommittee in Clinical Laboratory Hematology, 1991-97
Transfusion Medicine Subcommittee, 1993-8
Chairman, Transfusion Medicine Education Program, 1997, 1998
International Outreach Initiative – Subcommittee for Asia

American Society for Apheresis

President, 1985
Board of Directors, 1981-7
Chairman, Clinical Applications Committee, 1983-7
Chairman, Scientific Program, 1984, 1990

FDA

Blood Products Advisory Committee, 2002 - present
Advisory Panel on Orphan Drugs
Blood donors at risk for AIDS - subject matter expert
Workshop on Criteria for Evaluation of Red Cell Substitutes, 1999
Workshop on Leukoreduction of Blood Components, 1999

Haemonetics Corporation

Medical Advisory Board, 1988-99

Board of Directors, 1998-2002

Institute of Medicine

Blood Safety Forum, 1994-95
Committee on Resuscitation Fluids, 1998

International Society of Blood Transfusion

Scientific Committee – Int'l Congress (2000) Vienna
BEST Working Party, 1999-present
Scientific Committee International Congress (2004 Edinburgh

Metropolitan Washington Blood Banks, Inc.

Board of Directors, 1979-82
Chairman, Committee on Regionalization, 1979-80

National Marrow Donor Program (NMDP)

President, NMDP Council, 1993-4
Board of Directors, 1992-95
Membership Committee, 1988-92
Research and Publications Committee, 1990-95
International Affairs Committee, 1990-92
Vice President for Donor Centers, NMDP Council, 1992-94

National Heart, Lung and Blood Institute

National Blood Resources Education Program
Chairman, Data Safety and Monitoring Committee,
TRAP Study, 1991-6
Chairman, Data Safety & Monitoring Committee, T-Cell
Depletion Trial, 1994-2002

National Institute on Aging

Clinical Research Subpanel, 1982-5

National Institute of Allergy and Infectious Diseases

Expert Panel on the Effects of Donor Pool Size on the Safety and Efficacy of Immunoglobulin Products, 1998

U.S. Public Health Service

Advisory Committee on Blood Safety and Availability,2001- present
PHS Executive Task Force on AIDS, Charlottesville,VA, 1988
Medical Review Board, 1982-96
USPHS Working Group on HTLV-I, 1988
Medical Board, Clinical Center, NIH, 1982-4, 1989-91
NIH Strategic Planning Committee (Molecular Medicine Initiative Subcommittee), 1992
Secretary's Committee on Clinical Center Options, 1995

U.S. Pharmacopeia

Committee of Revision, Chairman: Blood and Blood Products, 1995-2000
Committee of Experts – Chairman, Blood & Blood Product Standards, 2000-2005

World Apheresis Association

Board of Directors, 1993-5
Councillor - North America, 1986-88, 1992-4
Scientific Program Committee, 1984, 1986, 1992, 1994

World Health Organization

Consultant to Global Blood Program - 2001

Invited lecturer (including plenary or keynote lectures) at numerous national and international meetings.

Ad hoc reviewer for numerous scientific and medical journals.

BIBLIOGRAPHY:

PEER REVIEWED JOURNALS:

Klein HG, Bell W. Disseminated Intravascular Coagulation Occurring During Heparin Therapy. Ann Int Med 1974; 80-477-481.

Klein HG, Aledort LM, Bouma BN., et al. A Cooperative Study for the Detection of the Carrier State of Classic Hemophilia. N Engl J Med 1977; 296:959-962.

Klein HG. A Chimpanzee Breeding Colony for Hepatitis Research: J Med Primat 1978; 7:182-184.

Weiss GB, Nienhuis AW, McIntosh CL, Klein HG. Traumatic Cardiac Hemolytic Anemia as a Late complication of a Starr-Edwards Mital Valve Prosthesis. Arch Intern Med 1979; 139:373-375.

Klein HG, Faltz LA, McIntosh CL, Appelbaum F, Deisseroth AB, Holland PV. Surgical Hypothermia in a Patient with a Cold Agglutinin: Management by Plasma Exchange. Transfusion 1980; 20:354-357.

Miller DM, Winslow RM, Klein HG, Wilson KC, Statham NJ, Brown FL, Fulmer J. Improved Exercise Performance after Exchange Transfusion in Subjects with Sickle Cell Anemia. Blood 1980;56:1127-32.

Klein HG, Garner RJ, Miller DM, Rosen S, Statham NJ, Winslow RM. Automated Partial Exchange Transfusion in Sickle Cell Anemia. Transfusion, 1980; 20:578-84.

Sazama K, Klein HG, Davey RJ, Corash L. Intraoperative Hemolysis as the Initial Manifestation of Glucose-6-Phosphate Dehydrogenase Deficiency. Arch Intern Med 1980; 140:845-6.

Kolins J, Allgood JW, Burghardt D, Klein HG, McGinniss MH. Modification of B, I, i, and Lewis Antigens in a patient with DiGuglielmo's erythroleukemia. Transfusion 1980; 20:574-77.

Diamond WJ, Brown F, Bitterman P, Klein HG, Davey R, Winslow RM. Delayed Hemolytic Transfusion Reaction Presenting as Sickle Cell Crisis. Ann Int Med 1980; 93-231-34.

Coles SM, Klein HG, Holland PV. Alloimmunization in two multi-transfused patient populations: Sickle Cell Disease and Thalassemia Major. Transfusion 1981; 21:462-67.

Corash L, Klein HG, Deisseroth A, Shafer B, Rosen S, Beaman J, Griffith P, Nienhuis A. Selective Isolation of Young Erythrocytes for Transfusion Support of Thalassemia Major Patients. Blood 1981; 57-599-606.

Gadek JE, Klein HG, Holland PV, Crystal RG. Replacement Therapy of Alpha 1-antitrypsin Deficiency: Reversal of Protease-Imbalance within the Alveolar Structures of Piz Subjects. J Clin Invest 1981; 68-1158-65.

Kessler CV, Klein HG, Havlik RJ. Uncontrolled Thrombocythemia in Chronic Myeloproliferative Disorders. Brit J Haem 1982; 50(1):157-67.

Klein HG, Kessler C, Anderson KC, Loomis KF. Multiple Arterial and Venous Thromboemboli in a Male with Chronic Myelogenous Leukemia and Occult Metastatic Breast Carcinoma. South Med J. 1982; 75:745-747.

Lenes B, Klein HG, Lakatos E. Selective Removal of Sickle Cells with the IBM 2997 Continuous Flow Blood Cell Separator. J. Clin. Apheresis 1983; 1:64-70.

Young NS, Klein HG, Griffith P, Nienhuis AW. A trial of immunotherapy in aplastic anemia and pure red cell aplasia. J. Clin. Apheresis 1983: 1:95-103.

Reichert CM, Weisenthal LM, Klein HG. Delayed Hemorrhage Following Percutaneous Liver Biopsy. J. Clin. Gastroenterol. 1983; 5:263-266.

Bracey A, Klein HG, Chambers S, Corash L. Simplified Selective Isolation of Young Red Cells for Chronic Transfusion Support. Blood 1983; 61:1068-1071.

Winslow RM, Butler WM, Kark JA, Klein HG, Moo-Penn W. The effects of bloodletting on exercise performance in a subject with a high-affinity hemoglobin variant. Blood 1983; 62: 1159-1164.

Klein HG, McCurdy PR, Braine HG, MacPherson JL, Dowling RN. Centrifugal Leukocytapheresis and Thrombocytapheresis: Complications Related to Equipment and Technique. J. Clin. Apheresis 1983; 1:190-195.

Rose J, Klein H, Greenstein J, McFarlin D, Gerber L, McFarland H. Lymphocytapheresis in chronic progressive multiple sclerosis: Results of a preliminary trial. Ann Neurol 1983; 14:593-594.

Marti GE, Folks T, Longo DL, Klein HG. Concise review: Therapeutic Cytapheresis in chronic lymphocytic leukemia. J Clin Apheresis 1983; 1:243-248.

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Lane HC, Masur H, Longo DL, Klein HG, Rook AH, Quinnan GV, Steis RG, Macher A, Whalen G, Edgar LC, Fauci AS. Partial Immune Reconstitution in a Patient with the Acquired Immunodeficiency Syndrome. N Engl J Med 1984; 311: 1099-1109.

Rodgers GP, Bonner RF, Klein HG, Noguchi CT, Nienhuis AW, Schecter AN. Periodic Microcirculatory Flow in Patients with Sickle Cell Disease. N Engl J Med 1984; 311: 1534-8.

Grindon AJ, Tomasulo PA, Bergin JJ, Klein HG, Miller JD, Mintz PD. The Hospital Transfusion Committee: Guidelines for Improving Services. JAMA 1985; 253:540-543.

Winslow RM, Klein HG, Monge CC. Red cell mass in Andean natives with excessive polycythemia. Arch Biol Andina 13:85-94, 1984-85.

Winslow RM, Monge CC, Brown EG, Klein HG, Sarnquist F, Winslow NJ. The effect of hemodilution on O2 transport in high altitude polycythemia. J Appl Physiol 1985; 59(5): 1495-1502.

Tomasulo PA, Lenes BA, Noto TA, Klein HG, Menitove J. Automatic Special Case Consultations in Transfusion Medicine. Transfusion, 1986; 26:186-193.

Klein HG, Balow JE, Dau PC, Hamburger MI, Leitman SF, Pineda AA, and Tindal RSA: Clinical Application of Therapeutic Apheresis. J Clin Apheresis 1986; 3(7):1-93.

AuBuchon JP, Carter CS, Adde MA, Meyer DR, Klein HG. Optimization of Parameters for Maximization of Plateletpheresis and Lymphocytapheresis yields on the Haemonetics Model V50. J. Clin. Apheresis 1986; 3(2):103-110.

Stevenson HC, Stevenson GW, Leitman SF, Carter CS, Alvord G, Klein HG. The isolation of human mononuclear subsets by cytapheresis for laboratory research. Plasma Ther Transfus Technol 1986; 7:365-371.

Muul LM, Nason-Burchenal K, Carter CS, Cullis H, Slavin D, Hyatt C, Director EP, Leitman SF, Klein HG, Rosenberg SA. Development of an automated closed system for generation of human lymphokine activated killer (LAK) cells for use in adoptive immunotherapy. J Immunol Methods 1987; 101:171-181.

Carter CS, Leitman SF, Cullis H, Muul LM, Nason - Burchenal K, Rosenberg SA, Klein HG. Use of a continuous flow cell separator in density gradient isolation of lymphocytes. Transfusion 1987; 27:362-365.

Areman EM, Simonis T, Carter C, Read EJ, Klein HG. Bulk cryopreservation of lymphocytes in glycerol. Transfusion 1988; 28:151-156.

Rodgers GP, Schechter AN, Noguchi CT, Klein HG, Nienhuis AW, Bonner RF. Microcirculatory adaptations in sickle cell anemia. Reactive hyperemia response. Am J. Physiol 1990;258:

Kruskall MS, Mintz PD, Bergin JJ, Johnston MFM, Klein HG, Miller JD, Rutman R, Silberstein L. Transfusion therapy in emergency medicine. Ann Emergency Med 1988; 17:327-335.

Sloand EM, Kessler CM, McIntosh CL, Klein HG. Neutralization of heparin-induced anticoagulation with methylene blue. Thromb. Res. 1989, 54:677-86.

Carter CS, Leitman SF, Cullis H, Muul LM, Nason-Burchenal K, Rosenberg SA, Klein HG. Technical Aspects of lymphokine-activated killer cell production. J. Clin. Apheresis 1988; 2/3:113-117.

Leitman SF, Klein HG, Melpolder JJ, Shih JW, Read EJ, Harvarth L, Darr F, Foy JL, Alter HJ. Clinical implications of positive tests for antibodies to human immunodeficiency virus type 1 in asymptomatic blood donors. N Engl of Med 1989; 321:917-23.

Sloand EM, Fox SM, Banks SM, Klein HG. Preparation of IgA deficient platelets. Transfusion 1990; 30:322-326.

Loiacono B, Carter G, Leitman S, Klein HG. Efficacy of various methods of confidential unit exclusion in identifying potentially infectious blood donations. Transfusion 1989; 29:823-6.

DePalma L, Palmer R, Leitman SF, Dolan WD, Klein HG. Utilization patterns of frozen autologous red blood cells: experience in a referral center and a community hospital. Arch Pathol Lab Med 1990; 114:516-18.

Bergsten P, Amitai G, Kehrl J, Dhariwal KR, Klein HG, Levine M. Millimolar concentrations of ascorbic acid in purified human mononuclear leukocytes: depletion and reaccumulation. J Biol Chem 1990; 265:2584-2587.

Sloand EM, Klein HG. Effect of white cells on platelets during storage. Transfusion 1990; 30:333-338.

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Sloand EM, Sloand JA, Prodouz K, Klein HG, Yu MW, Harvath L, Fricke W. Reduction of platelet glycoprotein Ib in uremia. Brit J. Haem 1991; 77:375-81.

Fricke W, Alling D, Kimball J, Griffith P, Klein H. Lack of efficacy of tranexamic acid in thrombocytopenic bleeding. Transfusion 1991; 31:345-348.

Keilholz U, Klein HG, Korbling M, Brado B, Carter CS, Cullis H, Galin F, Hunstein W. Peripheral blood mononuclear cells collection from patients undergoing adoptive immunotherapy or peripheral blood-derived stem cell transplantation and from normal donors. J. Clin Apheresis 1991; 6:131-6.

Sloand EM, Klein HG, Pastakia KP, Pierce P, Prodouz KN. Effects of albumin on the inhibition of platelet aggregation by beta lactam antibiotics. Blood 1992; 79:2022-27.

Sloand EM, Klein HG, Banks SM, Vareldzis B, Merritt S, Pierce P. Epidemiology of thrombocytopenia in HIV infection. Eur J. Haem 1992; 48:168-172.

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Stroncek DF, Holland PV, Bartsch G, Bixby T, Simmons RG, Antin JH, Anderson KC, ASH PC, Bolwell BH, Hansen JH, Heal JM, Henslee-Downey PJ, Jaffe' ER, Klein HG, Lau PM, Perkins HA, Popovsky MA, Price TH, Rowley SD, Stehling LC, Weiden PL, Wissel ME, McCullough J. Experiences of the first 493 unrelated marrow donors in the National Marrow Donor Program. Blood 1993; 81:1940-46.

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Sloand EM, Alyono D, Klein HG, Chang P, Yu M, Lightfoot FG, Kessler C. 1-Deamino-8-D-arginine vasopressin (DDAVP) increases platelet membrane expression of glycoprotein 1b in patients with disorders of platelet function and after cardiopulmonary bypass. Am J. Hematol 1994; 46: 199-207.

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Lee JH, Klein HG. The effect of donor erythrocyte sedimentation rate on efficiency of granulocyte collection by centrifugal leukapheresis. Transfusion 1995; 35:384-388.

Lee JH, Cullis H, Leitman SF, Klein HG. The efficacy of pentastarch in granulocyte collection by centrifugal leukapheresis. J Clin Apheresis. 1995;10:198-202.

Lee JH, Leitman SF, Klein HG. A controlled comparison of the efficacy of hetastarch and pentastarch in granulocyte collections of centrifugal leukapheresis. Blood 1995; 86:4662-6.

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Walker RE, Carter CS, Muul L, Natasajan V, Herpin BR, Leitman SF, Klein HG, Mullen CA, Baseler M, Falloon J, Davey Jr RT, Kovacs JA, Polis MA, Masur H, Blaese RM, Lane HC. Peripheral expansion of mature T Cells is a major means of CD4+ T cell regeneration in adults with HIV-1 infection. Nature Med. 1998, 4:852-6.

Silva N, O'Bryan L, Medeitos E, Holand H, Suliman J, Patronas N, Reed SG, Klein HG, Masur H, Badaro R, Trypanosoma Cruzi meningoencephalitis in HIV-infected patients. J. Acquir Immun Defic Syndr Hum Retrovirol 1999; 20:342-9.

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ASSOCIATION BULLETIN
#99-10

Date: December 2, 1999

To: AABB Institutional Members

From: Paul Ness, MD, President; Karen Shoos Lipton, JD, Chief Executive Officer

Re: New Uniform Donor History Questionnaire Issued

The uniform donor history questionnaire has been prepared by the AABB Blood Bank/Transfusion Service Standards Program Unit of the Standards Program Committee. The AABB Board of Directors has charged this committee to update the questionnaire as needed to be consistent with AABB Standards and Food and Drug Administration (FDA) requirements. This version of the questionnaire supersedes the existing questionnaire, which was issued on June 12, 1998, as Association Bulletin #98-3. It was amended on February 16, 1999, in Association Bulletin #99-5. This revision complies with the 19th edition of *Standards for Blood Banks and Transfusion Services.*

The donor screening process is an important tool that is designed to help safeguard the nation's blood supply. It is imperative that screening be performed consistently to prevent unsuitable donor candidates from donating. The process must be comprehensive, comprehensible and educational.

The questions have been prepared to assist in developing uniform guidelines for blood donor screening nationwide. They have been carefully worded to convey content simply and briefly, and have been reorganized into logical groupings. Changes made since the last version reflect the deliberations and decisions of the Standards Program Committee and recent statements issued by the FDA. New questions have been added, cites have been updated and comments have been revised so it is recommended that blood establishments review this questionnaire in its entirety.

The FDA has reviewed and approved the questionnaire, which is in compliance with the current FDA regulations/recommendations for donor suitability. The FDA further stated that "when distributing this questionnaire to your membership, it would be prudent to remind them to use it *in toto, without modifications.*" (Emphasis added by the AABB.)

Licensed blood establishments need to report changes in the donor history questionnaire in accordance with 21 CFR 601.12 (Changes to an approved application). Implementation of the FDA-approved AABB uniform donor history questionnaire without modification is reported in an establishment's annual report (21 CFR 601.12(d)).

You may be aware that the donor screening process has come under increasing public scrutiny, and has been discussed at recent meetings of the FDA Blood Products Advisory Committee and the Public Health Service's Advisory Committee on Blood Safety and Availability. These discussions have focused on the need for uniform donor screening throughout the country.

Although the questionnaire is not an AABB requirement and is provided as a tool to help members with compliance on donor screening, the AABB strongly recommends that each member institution administer the questions, as written, as part of its donor screening process.

*AABB members may also view this document by going to the AABB Web site: *www.aabb.org*. In the Member section of the Web page, click on Library and see the Association Bulletin section.

** The first Association Bulletin of each calendar year provides a listing of Association Bulletins. For copies of AABB association policy statements, including the Technical Bulletins and Joint Statements, fax a request to the Executive Secretary in the AABB Executive Office, (301) 907-6895.

Donor History Questions	American Association of Blood Banks (AABB)	Food and Drug Administration (FDA)	Comments
1. Have you ever donated or attempted to donate blood using a different (or another) name here or anywhere else?	Blood collection facilities shall confirm donor identity and link the donor to existing donor records. (Standard B2.100)	A record shall be available from which unsuitable donors may be identified so those products from such individuals will not be distributed. (21 CFR 606.160(e) April 1999)	
2. In the past 8 weeks, have you given blood, plasma or platelets here or anywhere else?	Frequency of whole blood donation is every eight weeks. (Standard B1.300)	Frequency of blood donation is every 8 weeks unless otherwise approved by the medical director (21 CFR 640.3(f) April 1999)	Infrequent plasma donors can donate every four weeks. (FDA Memos 3/10/95[1] and 12/14/95[2])
3. Have you for any reason been deferred or refused as a blood donor or told not to donate blood?	No specific requirement.	No specific requirement.	
4. Are you feeling well and healthy today?	The prospective donor shall appear to be in good health. (Standard B2.000)	Donor must be determined to be in good general health. (21 CFR 640.3(b) April 1999)	Requires "yes" answer that tests donor's attention to question context. Initiates sequence of personal health history questions (4-13).
5. In the past 12 months have you been under a doctor's care or had a major illness or surgery?	No specific requirements.	Persons who have received a transfusion of whole blood or a blood component within the past 12 months should not donate blood or blood components. (FDA Memo 4/23/92[3])	
6. Have you ever had chest pain, heart disease, recent or severe respiratory disease?	Prospective donors with diseases of the heart or lungs should be excluded unless determined to be suitable to donate by the blood bank medical director. (Standard B1.700)	Donor must be free of acute respiratory disease. (21 CFR 640.3(b)(4) April 1999)	
7. Have you ever had cancer, a blood disease or a bleeding problem?	Prospective donors with a history of cancer or abnormal bleeding tendency shall be excluded unless determined to be suitable to donate by the blood bank medical director. (Standard B1.700)	Persons with hemophilia or related clotting disorders who have received clotting factor concentrates must not donate blood or blood components. (FDA Memo 4/23/92[3])	
8. Have you ever had yellow jaundice, liver disease, viral hepatitis or a positive test for hepatitis?	Prospective donors with diseases of the liver shall be excluded unless determined to be suitable to donate by a blood bank physician. (Standards B1.700) Donors with a history of hepatitis after their 11th birthday or a confirmed test for HbsAg or a repeatedly reactive test for anti-HBc are indefinitely deferred. (Standard B2.711)	No individual with a history of hepatitis shall be source of whole blood donation. (21 CFR 640.3(c) April 1999) Exemptions for history of hepatitis before age 11. (FDA Memos 4/23/92[3] and 12/22/93[5])	
9. Have you ever had malaria, Chagas' disease or	Prospective donors who have had a diagnosis of	Prospective donors who have had malaria should	

babesiosis?	malaria shall be deferred for 3 years after becoming asymptomatic. (Standard B2. 741) A history of babesiosis or Chagas' disease shall be cause for indefinite deferral. (Standard B2.750)	be deferred for 3 years after becoming asymptomatic. (FDA Memo 7/26/94[6])	
10. A. Have you ever taken etretinate (Tegison) for psoriasis?	A. People who have received etretinate shall be deferred indefinitely. (Standard B2.520)	A. A donor who has taken or is taking Tegision should be permanently deferred. (FDA Memo 7/28/93[7])	A. Potentially teratogenic: may be present up to 3 years after last use.
B. In the past 3 years, have you taken Acitretin (Soriatane)?	B. Donor is to be Deferred for 3 years From date of last use. (Standard B2. 520)	B. Donor is to be deferred for 3 years from date of last dose (per manufacturer's insert.)	B. Potentially teratogenic. May be present up to 3 years after last use.
C. In the past 36 hours, have you taken aspirin, or anything that has aspirin in it?	C. Ingestion within 36 hours of donation of medications known to irreversibly damage platelet function (eg, aspirin-containing medications) or that inhibit platelet function and have a prolonged half-life should preclude the use of donor as the sole source of platelets for a recipient. (Standard B2.510)	C. No specific requirement for whole blood donation. Donors who have recently taken medication containing aspirin, especially within 36 hours, may not be suitable donors for platelet pheresis. (FDA Guidelines 10/7/88[8])	C. Preferred time varies. May be mandated by state health and safety code.
D. In the past month, have you taken Isotretinoin (Accutane) or finasteride (Proscar) (Propecia)?	D. For Accutane, Proscar, or Propecia, donor is to be deferred for 1 month after receipt of last dose. (Standard B2.520)	D. A donor taking Accutane or Proscar should be deferred from donating blood for at least one month after receipt of the last dose. (FDA Memo 7/28/93[7]) A donor taking Propecia should be deferred for one month. (FDA Telephone Communication to AABB, January 1998.)	D. Medication questions grouped.
E. In the past 4 weeks, have you taken any pills or medications?	E. Drug therapy shall be evaluated by a qualified person to determine suitability to donate blood. (Standard B1.900)	E. Facility medical director to determine donor acceptability or deferral based on medications. (FDA Memo 7/28/93[7])	E. Medication questions grouped. If donor answers "yes" to this question, see #1 below.
1. Have you at any time since 1980 injected bovine (beef) insulin?		1. As a precaution, the FDA recommends that blood donors who have injected bovine insulin since 1980 be indefinitely deferred unless it has been established that the	1. If the donor answers "yes" or "don't know" to the question, the FDA recommends that the donor be indefinitely deferred, unless it has been established that the product

		product was not manufactured since 1980 from cattle in the United Kingdom. (FDA Guidance for Industry, 11/23/99[9])	was not manufactured since 1980 from cattle in the United Kingdom. The FDA recommends that blood establishments review their policies regarding acceptance of insulin dependent diabetic patients as donors and their donor history questions to determine if or at which point in the interview process this question should be asked. The AABB recommends, however, that blood establishments maintain the current order to ensure uniformity of the questionnaire.
11. In the past 4 weeks, have you had any shots or vaccinations?	Donors must be queried about vaccines and immunizations. (Standard B2.600)	No specific requirement.	
12. In the past 12 months, have you been given rabies shots?	Donor is deferred for 12 months after vaccine for rabies if immunization is given after bite or other exposure to a potentially rabid animal. (Standard B2.600)	No specific requirement.	
13. Female donors: In the past 6 weeks, have you been pregnant or are you pregnant now?	Existing pregnancy or pregnancy in the past 6 weeks is cause for deferral. (Standard B1.800)	No specific requirement.	
14 A. In the past 3 years, have you been outside the United States or Canada?	A. Residents of countries in which malaria is not considered endemic but who have been in an area in which malaria is considered endemic may be accepted as regular blood donors one year after return irrespective of the receipt of antimalarial prophylaxis. (Standard B2.743) Immigrants, refugees or citizens coming from a country in which malaria is considered endemic may be accepted as blood donors 3 years after departure. (Standard B2.742)	A. Travelers to an area considered endemic for malaria should not be accepted as donors of whole blood and blood components prior to one year after departure. After one year, donors free of unexplained symptoms suggestive of malaria may be accepted whether or not they have received antimalarial chemoprophylaxis. Immigrants, refugees and citizens of endemic countries should not be accepted as donors prior to 3 years after departure. After 3 years, donors free of unexplained symptoms suggestive of malaria may be accepted. (FDA Memo 7/26/94[6])	A. Initiates sequence of exposure-type questions (14-30).
B. Have you visited or lived in the United		B. The FDA believes that donors who have	B. The FDA recommends that within a facility,

Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man or the Channel Islands) from 1980 to 1996? If so, have you spent a total of six months or more from 1980 through 1996?		resided in the United Kingdom (as identified by these questions) may be at risk for acquiring nvCJD. As a precaution, the FDA recommends that donors who answer "yes" to this question be indefinitely deferred. (FDA Guidance for Industry 11/23/99[9])	current donors need only be questioned once, and new donors questioned at first donation only.
15 A. Have you ever received human pituitary-derived hormone?	A. Prospective donors who have a family history of Creutzfeldt-Jakob disease or who have received tissue or tissue derivatives known to be a possible source of Creutzfeldt-Jakob agent (eg, dura mater, pituitary growth hormone of human origin) shall be deferred indefinitely. (Standard B2.410)	A. The FDA recommends that any donor who has received injections of pit-hGH be permanently deferred. (FDA Memo 7/28/93[7], Guidance for Industry 11/23/99[9].)	A. If the donor is uncertain about his or her treatment, the following question may be asked: Was the hormone treatment given repeatedly by injection? Donors who answer "yes" should be deferred.
B. Have you received a dura mater (or brain covering) graft?		B. The FDA recommends that persons who have received transplants of dura mater be permanently deferred from donation. (FDA Guidance for Industry 11/23/99[9].)	
C. Have you or any of your blood relatives ever had Creutzfeldt-Jakob disease or have you ever been told that your family is at an increased risk for Creutzfeldt-Jakob disease?		C. The FDA recommends that donors at increased risk for CJD be indefinitely deferred and appropriately counseled. The FDA considers that donors who answer "yes" to any of these questions (15 a, b, or c) are at an increased risk for developing CJD. (FDA Guidance for Industry 11/23/99[9].)	C. If the donor is not familiar with the term Creutzfeldt-Jakob disease, this may be taken as a negative response. If the donor is deferred because of family history (one or more family members with CJD), that donor may be re-entered if they meet FDA reentry criteria. (FDA Guidance for Industry 11/23/99[9])
16. In the past 12 months, have you had close contact with a person with yellow jaundice or viral hepatitis, or have you been given Hepatitis B Immune Globulin (HBIG)?	Close contact with person who has viral hepatitis is a 12 month deferral. (Standard B2.724)	Close contact with person who has viral hepatitis is a 12 month deferral. (FDA Memo 4/23/92[10])	Close contact generally refers to cohabitation. The medical director should establish a policy for these potential donors. The FDA does not recommend deferral of a sexual partner of an HCV antibody positive individual. (FDA Communication to AABB, August 1999)
17. In the past 12 months, have you taken (snorted)	Intranasal use of cocaine is a 12-month deferral.		

cocaine through your nose?	(Standard B2.727)		
18. In the past 12 months, have you received blood or had an organ or tissue transplant or graft?	Prospective donors who during the preceding 12 months received blood, blood components or derivatives, or other human tissue known to be possible sources of blood-borne pathogens, shall be excluded. (Standards B2. 420, B2.430)	Persons who have received a transfusion of whole blood or a blood component within the past 12 months should not donate blood or blood components. (FDA Memo 4/23/92[3])	Includes immunization with RBCs.
19. In the past 12 months, have you had a tattoo applied, ear or skin piercing, acupuncture, accidental needlestick or come in contact with someone else's blood?	Prospective donors shall be deferred from donating blood or blood components for transfusion who, within the preceding 12 months, have a history of: 1) A tattoo. 2) Mucous membrane exposure to blood. 3) Nonsterile skin penetration with instruments or equipment contaminated with blood or body fluids. 4) Sexual or household contact with an individual with viral hepatitis. 5) Sexual contact with an individual with HIV or at high risk of HIV infection. (Standards B2.721, B2.722, B2.723, B2.724, B2.725)	Persons who have had any contact with blood and body fluids through percutaneous inoculation (such as injury or accidental needlestick) or through contact with an open wound, non-intact skin or mucous membrane during the preceding 12 months should be deferred. (FDA Memo 4/23/92[3])	
20. A. In the past 12 months, have you had a positive test for syphilis? B. In the past 12 months, have you had or been treated for syphilis or gonorrhea?	A history of syphilis or gonorrhea, treatment for either, or a reactive screening test for syphilis shall be cause for deferral for 12 months after completion of therapy. (Standard B2.340)	Persons who have had, or have been treated for, syphilis or gonorrhea during the preceding 12 months should not donate blood or blood components. Persons with a positive (STS) test should be deferred 12 months. (FDA Memo 12/12/91[11])	
21. In the past 12 months, have you given money or drugs to anyone to have sex with you?	Donor must be given educational material on AIDS high-risk activity, and such at-risk persons should refrain from donating blood. Donor screening shall include questions intended to identify persons at high risk for HIV infection and high risk for HIV transmission. Such high-risk persons shall be deferred as specified in FDA recommendations. (Standards B3.100, B2.730)	Men and women who have engaged in sex for money or drugs since 1977 and persons who have engaged in sex with such people during the preceding 12 months should not donate blood or blood components. (FDA Memo 4/23/92[3])	
22. A. At any time since 1977, have you taken money or drugs for sex? B. In the past 12 months, have you had sex, even once, with anyone who has taken money or drugs	Refer to question #21	Men and women who have engaged in sex for money or drugs since 1977 and persons who have engaged in sex with such people during the preceding 12 months should not donate blood or blood components. (FDA Memo 4/23/92[3])	

for sex?			
23. A. Have you ever used a needle, even once, to take drugs that were not prescribed by a doctor?	A. Stigmata of narcotic habituation is an indefinite deferral. The donor shall not have used a needle even once to take drugs other than those prescribed by his/her physician. (Standard B2.330)	A. Donor must be free from skin punctures or scars indicative of addiction to self-injected narcotics. (21 CFR 640.3(b)(7) April 1999) Past or present intravenous drug users should not donate blood or blood components. (FDA Memo 4/23/92[3])	
B. In the past 12 months, have you had sex, even once, with anyone who has used a needle to take drugs not prescribed by a doctor?	B. Refer to question #21.	B. Persons who have had sex with any person who is a past or present intravenous drug user should not donate blood or blood components for 12 months. (FDA Memo 4/23/92[3])	
24. Male donors: Have you had sex with another male, even once, since 1977?	Refer to question #21.	Men who have had sex with another man, even one time, since 1977 should not donate blood or blood components permanently. (FDA Memo 4/23/92[3])	
25. Female donors: In the past 12 months, have you had sex with a male who has had sex, even once, since 1977 with another male?	Refer to question #21.	Females who have had sex with men who have had sex with another man even one time since 1977 should not donate blood or blood components for 12 months. (FDA Memo 4/23/92[3])	
26. A. Have you ever taken clotting factor concentrates for a bleeding problem, such as hemophilia?	No specific requirement.	A. Persons with hemophilia or related clotting disorders who have received clotting factor concentrates should not donate blood or blood components. (FDA Memo 4/23/92[3])	
B. In the past 12 months, have you had sex, even once, with anyone who has taken clotting factor concentrates for a bleeding problem such as hemophilia?		B. Persons who have had sex with any person with hemophilia or related clotting disorders who have received clotting factor concentrates should not donate blood or blood components for 12 months. (FDA Memo 4/23/92[3])	
27. A. Do you have AIDS or have you had a positive test for the AIDS virus?	Refer to question #21.	A. Persons with clinical or laboratory evidence of HIV infection must not donate blood or blood components. (FDA Memo 4/23/92[3])	

B. In the past 12 months, have you had sex, even once, with anyone who has AIDS or has had a positive test for the AIDS virus?		B. Persons who have had sex with persons with clinical or laboratory evidence of HIV infection should not donate blood for 12 months. (FDA Memo 4/23/92[3])	
28. Are you giving blood because you want to be tested for HIV or the AIDS virus?	No specific requirement.	No specific requirement.	Direct question to further evaluate donation motive.
29. Do you understand that if you have the AIDS virus, you can give it to someone else even though you may feel well and have a negative AIDS test?	No specific requirement.	Donors should be informed that there is an interval during early infection when the HIV antibody test may be negative although the infection may still be transmitted. (FDA Memo 4/23/92[3])	Queries donor understanding of "Important Information for Donors."
30. A. Were you born in, have you lived in, or have you traveled to any African country since 1977? C. When you traveled to <country(ies)> did you receive a blood transfusion or any other medical treatment with a product made from blood? D. Have you had sexual contact with anyone who was born in or lived in any African country since 1977?	(Association Bulletin #97-5[13])	(FDA Memo 12/11/96[12])	A. If "no," proceed to the question (question c) about sexual contact. If "yes," the donor should be asked to name the specific country(ies). If the donor identifies an African country *not* listed in the FDA Memo, proceed to question C. If one or more of the countries listed in the FDA Memo is named by the donor, determine if the donor was born in, lived in, or traveled to the country(ies) named by the donor. If the donor was born in or lived in any of the FDA-identified countries, defer indefinitely; questioning stops here. If travel was the donor's risk, ask question B. The Central African Republic was the Central African Empire in the late 1970s. None of the other countries listed in the FDA Memo have undergone a change in name since 1977. Blood establishments should critically evaluate the potential donor's history and statements, and decide whether the individual could have been in the country long enough to have encountered those local conditions related to risk, such as use of unsterile needles or sexual contact. When donors report demographic HIV-1 Group O risks, no follow-up actions
30. Continued			

			regarding previously donated blood are necessary. A. If "no," proceed to Question c. If "yes," defer indefinitely. B. If "no," or the donor names a country not identified in the FDA Memo, no deferral. If "yes," ask the donor to specify which country(ies). If donor names country listed in the FDA Memo, defer indefinitely.
31. In the past 12 months, have you been in jail or prison?	Donors are deferred for 12 months if in the preceding 12 months they have been incarcerated in a correctional institution (jail or prison) for more than 72 consecutive hours. (Standard B2.726)	Individuals who have been incarcerated for more than 72 consecutive hours during the previous 12 months should be deferred as donors for 12 months from the last date of incarceration. (FDA Memo 6/8/95[14])	
32. Have you read and understood all the donor information presented to you, and have all your questions been answered?	No specific requirement.	Information should be written in language that assures that the donor understands the definition of high-risk behavior and the importance of self-exclusion. Donors should not be considered suitable unless information about risks can be communicated in the language appropriate to each donor and is constructed to be culturally sensitive to promote comprehension. (FDA Memo 4/23/92[4])	

Standards referred to are from the 19th edition of *Standards for Blood Banks and Transfusion Services*, effective June 1, 1999.

1. FDA Memorandum, March 10, 1995: Revision of FDA Memorandum of August 27, 1982: Requirements for Infrequent Plasma Donors.
2. FDA Memorandum, December 14, 1995: Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma.
3. FDA Memorandum, April 23, 1992: Revised Recommendations for the Prevention of HIV Transmission by Blood and Blood Products.
4. FDA Memorandum, April 23, 1992: Exemptions to Permit Persons with a History of Viral Hepatitis Before the Age of Eleven Years to Serve as Donors of Whole Blood and Plasma: Alternative Procedures, 21 CFR 640.120.
5. FDA Memorandum, December 22, 1993: Donor Suitability Related to Laboratory Testing for Viral Hepatitis and a History of Viral Hepatitis.
6. FDA Memorandum, July 26, 1994: Recommendation for Deferral of Donors for Malaria Risk.
7. FDA Memorandum, July 28, 1993: Deferral of Blood and Plasma Donors Based on Medications.
8. FDA Memorandum, October 7, 1988: Revised Guidelines for the Collection of Platelets, Pheresis.
9. Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products. November 23, 1999.
10. FDA Memorandum, April 23, 1992: Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV).

11. FDA Memorandum, December 12, 1991: Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing.
12. FDA Memorandum, December 11, 1996: Interim Recommendations for Deferral of Donors at Increased Risk for HIV-1 Group O Infection.
13. FDA Accepts AABB Changes to HIV-1 Group O Donor Questions. Association Bulletin #97-5, August 1, 1997.
14. FDA Memorandum, June 8, 1995: Recommendations for the Deferral of Current and Recent Inmates of Correctional Institutions as Donors of Whole Blood, Blood Components, Source Leukocytes, and Source Plasma.

Abbreviated Donor History Questionnaire

	Yes	No	
1. Are you feeling healthy and well today?	☐	☐	
2. Have you read the educational materials and had your questions answered?	☐	☐	
In the past **48 hours**			
3. Have you taken aspirin or anything that has aspirin in it?	☐	☐	
In the past **6 weeks**			
4. Female donors: Have you been pregnant or are you pregnant now? (Males: check "I am male.")	☐	☐	☐ I am male
In the past **8 weeks** have you			
5. Donated blood, platelets or plasma?	☐	☐	
6. Had any vaccinations or other shots?	☐	☐	
7. Had close contact with the smallpox vaccination site of someone else?	☐	☐	
In the past **16 weeks**			
8. Have you donated a double unit of red cells using an apheresis machine?	☐	☐	
Since your **last donation** have you			
9. Had any new medical problems or diagnoses?	☐	☐	
10. Had any new medical treatments?	☐	☐	
11. Taken any of the medications on the Medication Deferral List?	☐	☐	
12. Been outside the United States or Canada?	☐	☐	
13. Come into contact with someone else's blood?	☐	☐	
14. Had an accidental needle-stick?	☐	☐	
15. Had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?	☐	☐	
16. Had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?	☐	☐	
17. Had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?	☐	☐	
18. Had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?	☐	☐	
19. Female donors: had sexual contact with a male who has ever had sexual contact with another male? (Males: check "I am male.")	☐	☐	☐ I am male
20. Had sexual contact with anyone who was born in or lived in Africa?	☐	☐	
21. Come into contact with blood from a person who has hepatitis?	☐	☐	
22. Had sexual contact with a person who has hepatitis?	☐	☐	
23. Lived with a person who has hepatitis?	☐	☐	
24. Received money, drugs, or other payment for sex?	☐	☐	
25. Male donors: had sexual contact with another male, even once? (Females: check "I am female.")	☐	☐	☐ I am female
26. Had a tattoo?	☐	☐	
27. Had ear or body piercing?	☐	☐	
28. Been in juvenile detention, lockup, jail, or prison for more than 72 hours?	☐	☐	
29. Used needles to take drugs, steroids, or anything not prescribed by your doctor?	☐	☐	
30. Have any of your relatives had Creutzfeldt-Jakob disease?	☐	☐	

American Red Cross

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BLOOD DONATION ELIGIBILITY GUIDELINES

Note to users: *This list is not complete. Medical professionals are available at each blood collection center and details of each donor's health and activities are discussed in a confidential setting prior to blood donation. The final determination of eligibility is made at that time. Some donor eligibility rules are specified by the Food and Drug Administration for every blood bank in the country. Other rules are determined by the particular blood bank and may differ between programs. Donor eligibility rules are intended to protect the health and safety of the donor as well as the patient who will receive the transfusion. The criteria listed below are provided as guidelines to assist you in determining whether you may be eligible to be a blood donor. The guidelines listed below were last revised on 6/27/02. There may have been some changes to these criteria since the last revision date. The most up to date eligibility information can be obtained by contacting the American Red Cross blood center nearest you.*

GENERAL GUIDELINES

To give blood for transfusion to another person, you must be healthy, be at least 17 years old, weigh at least 110 pounds, and not have donated blood in the last 56 days. "Healthy" means that you feel well and can perform normal activities. If you have a chronic condition such as diabetes or high blood pressure, "healthy" also means that you are being treated and the condition is under control.

Other aspects of each potential donor's health history are discussed as part of the donation process before any blood is collected. Each donor receives a brief examination during which temperature, pulse, blood pressure and blood count (hemoglobin or hematocrit) are measured.

Making donations for your own use during surgery (autologous blood donation) is considered a medical procedure and the rules for eligibility are less strict than for regular volunteer donations.

Accupuncture
Age
Hepatitis, Jaundice
Hepatitis Exposure

Allergy, Stuffy Nose, Itchy Eyes, Dry Cough
Antibiotics
Aspirin
Asthma
Autoimmune Diseases
Birth Control
Blood Pressure, High
Blood Pressure, Low
Blood Transfusion
Cancer
Cholesterol, high
Chronic Illnesses
Clotting Disorders
Cocaine
Cold, Flu, Sore Throat
Creutzfeldt-Jakob Disease (CJD)
Creutzfeldt-Jakob Disease, Variant (vCJD); "Mad Cow Disease"
Dental Procedures
Depression, Anxiety
Diabetes mellitus
Donation Intervals
Epilepsy, Seizures
Heart Disease
Heart Murmur, Heart Valve Disorder
Hemochromatosis
Hemoglobin, Hematocrit, Blood Count
Herpes
HIV, AIDS
Hormone Replacement Therapy (HRP)
Human Papilloma Virus (HPV)
Hypertension, High Blood Pressure
Immunization, Vaccination
Infections
Infectious Mononucleosis, "Mono"
Intravenous Drug Use
Lyme disease
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Marijuana, "Weed", "Pot"
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Menstruation
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Piercing (ears, body), Electrolysis
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Sickle Cell
Skin Disease, Rash, Acne
Surgery
Syphilis/Gonorrhea
Tattoo
Tuberculosis
Travel Outside of U.S., Immigration
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Weight

Accupuncture
Donors who have undergone acupuncture treatments are acceptable as long as the donor can confirm that the needles used in the treatment were sterile. Donors who cannot confirm that sterile needles were used in the acupuncture treatment are deferred from donating for 12 months.

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Age
You must be at least 17 years old to donate to the general blood supply. Learn more about the reasons for a lower age limit. There is no upper age limit for blood donation as long as you are well with no restrictions or limitations to your activities.

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Allergy, Stuffy Nose, Itchy Eyes, Dry Cough
Acceptable as long as you feel well, have no fever, and have no problems breathing through your mouth

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Antibiotics
Wait 2 days after finishing antibiotics for an infection (bacterial or viral). Acceptable if you are taking antibiotics to prevent an infection, for example, following dental procedures or for acne. Antibiotics for acne do not disqualify you from donating. If you have a temperature above 99.5 F, you may not donate until the fever is passed.

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Aspirin
See "Medications"

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Asthma
Acceptable as long as you are not having difficulty breathing at the time of donation and you otherwise feel well. Medications for asthma do not disqualify you from donating.

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Autoimmune Diseases
You are not eligible to donate if you have some types of generalized autoimmune disease including systemic lupus erythematosus and multiple sclerosis.

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Birth Control
Women taking birth control pills are acceptable.

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Blood Pressure, High
Acceptable as long as your blood pressure is below 180 systolic (first number) and below 100 diastolic (second number) at the time of donation. Medications for high blood pressure do not disqualify you from donating.

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Blood Pressure, Low
Acceptable as long as you feel well when you come to donate. If your blood pressure normally runs low, it may be more difficult for your body to adjust to the volume loss following donation, especially if you are dehydrated. Drinking extra water before and after donation is important.

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Blood Transfusion
Wait for 12 months after receiving a blood transfusion from another person in the United States. You may not donate if you received a transfusion since 1980 in the United Kingdom (England, Wales, Scotland, Northern Ireland, Channel Islands, Isle of Man), Gibraltar or Falkland Islands. This requirement is related to concerns about variant CJD, or 'mad cow' disease. Learn more about variant CJD and blood donation.

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Cancer
Acceptable if the cancer was treated with only surgery or radiation, and it has been at least 5 years since treatment was completed with no cancer recurrence. If your cancer was treated with chemotherapy, hormonal therapy or immunotherapy, you are not eligible to donate. If you had leukemia or lymphoma, including Hodgkins Disease, you are not eligible to donate. Some low-risk cancers including squamous or basal cell cancers of the skin do not require a 5 year waiting period.

Precancerous conditions of the uterine cervix do not disqualify you from donation if the abnormality has been treated successfully.

You should discuss your particular situation with the health historian at the time of donation.

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Cholesterol, high
Acceptable. Medications to lower the cholesterol level do not disqualify you from donating.

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Chronic Illnesses
Most chronic illnesses are acceptable as long as you feel well, the condition is under good control, you have an adequate hemoglobin level and your temperature is normal when you come to donate. Chronic fatigue syndrome, fibromyalgia, rheumatoid arthritis, hypothyroidism, ulcerative colitis and Crohn's Disease do not automatically disqualify you from donating. You should discuss your condition with the health historian at the time of donation.

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Clotting Disorders
If your blood does not clot normally, you should not donate since you may have excessive bleeding where the needle was placed. For the same reason, if you are taking any "blood thinner" (such as coumadin or heparin) you should not donate. If you are on aspirin, it is OK to donate blood. However, you must be off of aspirin for at least 36 hours in order donate platelets by apheresis.

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Cocaine
Wait 12 months after using cocaine or other street drugs through your nose before attempting to donate blood. This requirement is related to concerns about hepatitis and HIV. Learn more about hepatitis and blood donation.

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Cold, Flu, Sore Throat
Wait if you have a fever or a productive cough (bringing up phlegm)
Wait if you feel unwell on the day of donation.
Wait 2 days after you have completed antibiotic treatment for sinus, throat or lung infection.

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Creutzfeldt-Jakob Disease (CJD)
If you ever received a corneal (eye) transplant, a dura mater (brain covering) transplant or human pituitary growth hormone, you are not eligible to donate. Those who have a close blood relative who had Creutzfeld-Jacob disease or who is in a family that has been told they have a genetic risk for Creutzfeld-Jacob disease are also not eligible to donate. Learn more about CJD.

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Creutzfeldt-Jakob Disease, Variant (vCJD); "Mad Cow Disease"
See under Travel Outside of U.S. Learn more about vCJD and blood donation.

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Dental Procedures
Acceptable after teeth cleaning, scaling, root canal, fillings and tooth extractions as long as there is no infection present.
Wait for 3 days after having other types of oral surgery, or after treatment for an abscess or infection in the mouth.
Wait 2 days after finishing antibiotics for a dental infection.

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Depression, Anxiety
Acceptable as long as you feel well and comfortable with the blood donation process.
Medications for depression or anxiety do not disqualify you from donating.

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Diabetes mellitus
Acceptable two weeks after starting insulin.
Medications to lower your glucose level do not disqualify you from donating. Those who since 1980, received an injection of bovine (beef) insulin made from cattle from the United Kingdom are not eligible to donate. This requirement is related to concerns about variant CJD, or 'mad cow' disease. Learn more about variant CJD and blood donation.

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Donation Intervals
Wait at least 8 weeks between whole blood (standard) donations.
Wait at least 3 days between plateletpheresis donations.
Wait at least 16 weeks between double red cell (automated) donations.

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Epilepsy, Seizures
Acceptable as long as you have been seizure-free for the last 3 months. Medications for seizures do not disqualify you from donating.

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Heart Disease
In general , acceptable as long as you have no restrictions on your physical activities, take no medications for heart disease other than aspirin, and have no current (within the last 6 months) heart-related symptoms such as chest pain.
Wait at least 6 months following an episode of angina.
Wait at least 6 months following a heart attack.
Wait at least 6 months after bypass surgery or angioplasty.
If you have a pacemaker, you may donate as long as your pulse is between 50 and 100 beats per minute with no more than a small number of irregular beats, and you meet the other heart disease criteria. You should discuss your particular situation with the health historian at the time of donation.

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Heart Murmur, Heart Valve Disorder
Acceptable if you have a heart murmur as long as you have not had symptoms in the last 6 months, have no restrictions on your physical activity and are not taking any medications for heart disease other than prophylactic antibiotics (to prevent infections) or aspirin.

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Hemochromatosis
American Red Cross does not accept individuals with hemochromatosis as blood donors for other persons at this time. Red Cross will continually re-evaluate this policy as more information accumulates.

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Hemoglobin, Hematocrit, Blood Count
Acceptable if you have a hemoglobin at or above 12.5 g/dL.
Acceptable if you have a hematocrit at or above 38%.

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Hepatitis, Jaundice
If you had hepatitis (inflammation of the liver) caused by a virus, or unexplained jaundice (yellow discoloration of the skin), since age 11, you are not eligible to donate blood. This includes those who had hepatitis with infectious mononucleosis.

Acceptable if you had jaundice or hepatitis caused by something other than a viral infection, for example: medications, Gilbert's disease, bile duct obstruction, alcohol, gallstones or trauma to the liver.

If you ever tested positive for hepatitis B or hepatitis C , at any age, you are not eligible to donate, even if you were never sick or jaundiced from the infection.

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Hepatitis Exposure
Wait 12 months after close contact with someone who is sick with viral hepatitis. Close contact is defined as sexual contact or sharing the same household, kitchen, dormitory, or toilet facilities.

Wait 12 months after detention in a correctional institution or residence in a long-term psychiatric institution.

Wait 12 months after receiving a blood transfusion (unless it was your own "autologous"

blood, blood injections, tattoo, non-sterile needle stick/body piercing or exposure to someone else's blood.

Wait 12 months following a human bite, if it broke the skin.

Wait 12 months after using cocaine or other street drugs through your nose.

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Herpes
Acceptable as long as you are feeling well.

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HIV, AIDS
Those who are at increased risk for becoming infected with HIV are not eligible to donate blood. According to the Food and Drug Administration, you are at increased risk if:

- you are a male who has had sex with another male since 1977, even once;
- you have ever used a needle, even once, to take drugs or steroids that were not prescribed by a physician;
- you have taken clotting factor concentrates for a bleeding disorder such as hemophilia;
- you were born in or lived in Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria since 1977 (This requirement is related to concerns about HIV Group O. Learn more about HIV Group O.)
- you have taken drugs or money in exchange for sex since 1977;
- you have ever had a positive test for HIV virus;
- you have symptoms of HIV infection including unexplained weight loss, night sweats, blue or purple spots on or under the skin, long-lasting white spots or unusual sores in your mouth, lumps in your neck, armpits, or groin that last more than a month, fever higher than 99 degrees that lasts more than 10 days, diarrhea lasting over a month, or persistent cough and shortness of breath;

Wait for 12 months after close contact with someone who is at an increased risk for HIV infection. This occurs when paying to have sex, as a result of rape, or when having sex with an IV drug user.

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Hormone Replacement Therapy (HRP)
Women on hormone replacement therapy for menopausal symptoms and prevention of osteoporosis are eligible to donate.

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Human Papilloma Virus (HPV)
See "Venereal Diseases"

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Hypertension, High Blood Pressure
See "Blood Pressure, High

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Immunization, Vaccination
Acceptable if you were vaccinated for influenza, tetanus or meningitis, providing you are symptom-free and fever-free.

Wait 4 weeks after immunizations for German Measles (Rubella), MMR (Measles, Mumps and Rubella) and Chicken Pox.

Wait 2 weeks after immunizations for Red Measles (Rubeola), Mumps, Polio (by mouth), and Yellow Fever vaccine.

Wait 7 days after immunization for Hepatitis B as long as you are not given the immunization for exposure to hepatitis B.

- **Smallpox vaccination and did not develop complications**
  Wait 2 months (60 days) from the date of having a smallpox vaccination as long as you have had no complications. Complications may include skin reactions beyond the vaccination site or general illness related to the vaccination.
- **Smallpox vaccination and developed complications**
  Wait 14 days after all vaccine complications have resolved or 2 months (60 days) from the date of having had the smallpox vaccination whichever is the longer period of time. You should discuss your particular situation with the health historian at the time of donation. Complications may include skin reactions beyond the vaccination site or general illness related to the vaccination.
- **Smallpox vaccination – close contact with someone who has had the smallpox vaccine in the last eight weeks and you did not develop any skin lesions or other symptoms.**
  Eligible to donate.
- **Smallpox vaccination – close contact with someone who has had the vaccine in the last eight weeks and you have since a developed localized skin lesion only**
  Wait 2 months (60 days) from the date of the first skin lesion or sore. You should discuss your particular situation with the health historian at the time of donation. Complications may include skin reactions or general illness related to the exposure.
- **Smallpox vaccination – close contact with someone who has had the vaccine in the last eight weeks and you have since developed localized skin lesions and other complications**

Wait 14 days after all vaccine complications have resolved or 2 months (60 days) from the date of the first symptom whichever is the longer period of time. You should discuss your particular situation with the health historian at the time of donation. Complications may include skin reactions or general illness related to the exposure.

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Infections
If you have a fever or an active infection, wait until the infection has passed before donating blood.

Wait 2 days after finishing antibiotics for an infection (bacterial or viral).

Infections with common herpes virus (cold sores or genital herpes) and Human Papilloma Virus (HPV) are acceptable as long as you feel well and do not have a fever.

Those who have had infections with Chagas Disease, babesiosis or leishmaniasis are not eligible to donate blood.

See also Antibiotics, Infectious Mononucleosis, Hepatitis, HIV, Syphilis/Gonorrhea, and Tuberculosis.

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Infectious Mononucleosis, "Mono"
Acceptable if you had infectious mononucleosis ("mono") once the infection has passed, as long as you did not have hepatitis with the mononucleoisis.

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Intravenous Drug Use
Those who have ever used IV drugs that were not prescribed by a physician are not eligible to donate. This requirement is related to concerns about hepatitis and HIV. Learn more about hepatitis and blood donation.

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Lyme disease
If this is a chronic condition you cannot donate. If you were treated with antibiotics and completely recovered, you can donate 12 months after the last dose of antiobiotics was taken.

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Malaria
Wait 3 years after completing treatment for malaria. Wait 12 months after returning from a trip to an area where malaria is found. Wait 3 years after moving to the United States after living in a country where malaria is found. Learn more about malaria and blood donation.

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Marijuana, "Weed", "Pot", "Ganga"
Acceptable as long as you are not under the influence of marijuana at the time of donation.

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Medications In almost all cases, medications will not disqualify you as a blood donor. Your eligibility will be based on the reason that the medication was prescribed. As long as the condition is under control and you are healthy, blood donation is usually permitted.

There are a handful of drugs that are of special significance in blood donation. Persons on these drugs have waiting periods following their last dose before they can donate blood:

- Accutane (isoretinoin), Proscar (finasteride), and Propecia (finasteride) - wait 4 weeks .
- Arava (leflunomide) - wait 3 months
- Avodart (dutasteride) - wait 6 months from the last dose
- Aspirin, no waiting period for donating blood. However you must wait 36 hours after taking aspirin or any medication containing aspirin before donating platelets by apheresis
- Chemotherapy-type drugs used for conditions other than cancer (examples: bleomycin, interferon, methotrexate) - wait 4 weeks from last dose
- Coumadin, heparin or other prescription blood thinners- you should not donate since your blood will not clot normally. If your doctor discontinues your treatment with blood thinners, wait 5 days before returning to donate.
- human pituitary-derived growth hormone at any time - you are not eligible to donate blood
- Lupron used for condition other than cancer - wait 4 months from last dose
- Plavix - wait 36 hours after taking this medication before donating platelets by apheresis
- Soriatane (acitretin) - wait 3 years
- Tegison (etretinate) at any time - you are not eligible to donate blood
- Ticlid - wait 36 hours after taking this medication before donating platelets by apheresis

If you ever took Tegison (etretinate), you are not eligible to donate blood. If you ever took human pituitary-derived growth hormone, you are not eligible to donate blood. If you take aspirin, you can donate blood. However you must wait 36 hours after taking aspirin or any medication containing aspirin before donating platelets by apheresis. If you take Ticlid or Plavix, wait 36 hours after taking these medications before donating platelets by apheresis. If you are taking prescription blood thinners such as Coumadin or heparin, you should not

donate since your blood will not clot normally. If your doctor discontinues your treatment with blood thinners, wait 5 days before returning to donate.

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Menstruation
Women may donate during their period if feeling well on the day of donation.

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Organ/Tissue Transplants
Wait 12 months after receiving an organ or tissue transplant from another person. This includes bone and dental powder. If you are taking medications to prevent rejection of the organ or tissue you are not eligible to donate.

If you ever received a corneal (eye) transplant or a dura mater (brain covering) transplant, you are not eligible to donate. This requirement is related to concerns about the brain disease, Creutzfeld-Jacob Disease (CJD). Learn more about CJD and blood donation.

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Piercing (ears, body), Electrolysis
Acceptable as long as the instruments used were sterile.

Wait 12 months if there is any question whether or not the instruments used were sterile and free of blood contamination. This requirement is related to concerns about hepatitis. Learn more about hepatitis and blood donation.

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Pregnancy, Nursing
Persons who are pregnant are not eligible to donate. Wait 6 weeks after giving birth.
Acceptable if you are nursing, or recently had an elective abortion.

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Sexually Transmitted Disease
Wait 12 months after treatment for syphilis or gonorrhea.

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Sickle Cell

Acceptable if you have sickle cell trait. Those with sickle cell disease are not eligible to donate.

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Skin Disease, Rash, Acne
Acceptable as long as the skin over the vein to be used to collect blood is not affected. If the skin disease has become infected, wait until the infection has cleared before donating. Taking antibiotics to control acne does not disqualify you from donating.

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Surgery
Acceptable once the wound is healed and stitches are dissolved or removed, as long as the underlying condition is also acceptable in a blood donor. Wait 2 days after having stitches or staples for lacerations. If a laceration has become infected, wait until the infection has cleared before donating. Wait 12 months if you had a blood transfusion from another person during surgery.

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Syphilis/Gonorrhea
Wait 12 months after being treated for syphilis or gonorrhea.

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Tattoo
Wait 12 months after a tattoo. This requirement is related to concerns about hepatitis. Learn more about hepatitis and blood donation.

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Tuberculosis
Acceptable if you have a positive skin test for tuberculosis, or if you are receiving antibiotics for a positive TB skin test only. If you are being treated for a tuberculosis infection, wait until treatment is successfully completed before donating.

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Travel Outside of U.S., Immigration
Wait 12 months after travel in an area where malaria is found. Wait 3 years after moving to the United States after living in a country where malaria is found. Persons who have spent long periods of time in countries where "mad cow disease" is found are not eligible to donate.

This requirement is related to concerns about variant Creutzfeld Jacob Disease (vCJD). Learn more about vCJD and donation. Persons who were born in or who lived in certain countries in Western Africa, or who have had close contact with persons who were born in or who lived in certain West African countries are not eligible to donate. This requirement is related to concerns about HIV Group O. Learn more about HIV Group O, and the specific African countries where it is found.

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Venereal Diseases
See also "Sexually Transmitted Disease"
Wait 12 months after treatment for syphilis or gonorrhea.

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Weight
You must weigh at least 110 Lbs to be eligible for blood donation for your own safety. Blood volume is in proportion to body weight. Donors who weight less than 110Lbs may not tolerate the removal of the required volume of blood as well as those who weigh more than 110Lbs. There is no upper weight limit as long as your weight is not higher than the weight limit of the donor bed/lounge you are using. You can discuss any upper weight limitations of beds and lounges with your local health historian.

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Last updated: 6/27/02
By: R.A.R.,MD and M.A.P., RN,BSN

Note to users: *Eligibility guidelines may have changed since this information was last updated. For current information, please contact the American Red Cross blood region nearest you.*

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Apheresis

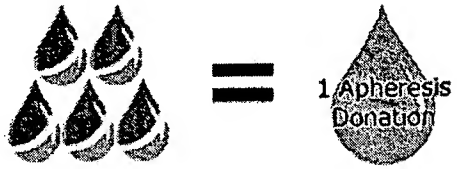
In an apheresis (ay-fur-ee-sis) donation, from the Greek "to take away," donors give only select blood components — platelets, plasma, red cells, infection-fighting white cells called granulocytes, or a combination of these, depending on the donors' blood type and the needs of the community. Apheresis is most commonly used to collect platelets and plasma.

"By donating blood, I can serve my country in a very easy way."
— Laura

Patient Benefits
A single apheresis donation of platelets can provide as many platelets as 5 whole blood donations. In addition, a platelet transfusion from a single donor greatly reduces the chances of an immune system reaction to the transfusion. Bone marrow transplant, cancer and leukemia patients whose immune systems are already compromised, benefit particularly from single donor platelet transfusions.

Apheresis donors' donations go through additional typing called Human Leukocyte Antigen (HLA) typing to ensure that the match between donor and recipient is as close as possible. Donors are then matched with specific patients in hospitals. Apheresis donors may receive emergency requests to donate for a patient to whom they are matched. Many apheresis donors find the knowledge that they are helping a specific individual in need particularly rewarding.

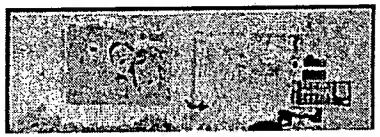
Whole Blood vs. Apheresis

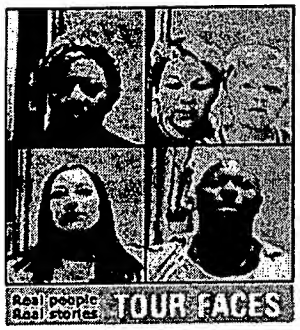


People who donate just platelets can donate every 3 days for a maximum of 24 times a year.

Who Can Be an Apheresis Donor?
The same good health requirements that govern whole blood donors apply to apheresis donors. You must be at least 17 years old, weigh at least 110 pounds and be in good health.

The Apheresis Donation Process: Safe and Easy
Similar to a whole blood donation, an aphersis donation consists of four steps: registration, health history and mini-physical, donation, and refreshments. From registration to refreshments, the process





lasts 1½ -2½ hours. During the actual donation, you will sit in a comfortable recliner, and a carefully monitored machine will draw blood from one arm through sterile tubing into a cell separator centrifuge. The blood stays inside the self-contained sterile tubing and never comes in contact with the machine. After the blood component(s) have been collected, the rest of the blood is returned to the donor through the same arm or the other arm. It's a safe process — the collection sets and needles are sterile, used once for each donor and then discarded. Donors usually relax, read, or enjoy a movie during the donation.

Signing up
Apheresis donations are by appointment only — call 1-800-GIVE LIFE to schedule an appointment.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GOODNOW

Serial No: 09/616,283

Filed: July 14, 2000

For: SYSTEM FOR DETECTING BACTERIA IN BLOOD, BLOOD PRODUCTS, AND FLUIDS OF TISSUES

Art Unit: 1645

Attorney Docket No. VRXB-P01-001

Examiner: J. Hines

Assistant Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration Under 37 C.F.R. §1.132

Sir:

I, Stephen J. Wagner, Ph.D., of Columbia, Maryland, hereby declare as follows:

1. I am the Director of Cell Therapy at the Holland Laboratory of the American Red Cross. I have been conducting research in the field of transfusion medicine for over 14 years. Accordingly, my curriculum vitae is attached as Appendix A.

2. I have read the above-identified application, the pending claims, and the Office Action mailed on September 29, 2003.

3. I understand that the Examiner has stated that the invention as described and claimed in the above-identified application is obvious in view of the teachings of Fisher et al. WO 98/57994, McLaughlin (U.S. Patent 4,683,196), Tadler et al. (*J. Clin. Lab. Anal.* 3: 21-25 (1989)), Erich et al. (*J. Immunol.* 143(12): 4053-4060, 1989), and Chang et al. (U.S. Patent 5,200,323).

For the reasons stated below, I respectfully disagree with the Examiner. I have been working in the field of transfusion medicine for over fourteen (14) years. During this time, the issue of bacterial contamination has been a source of primary concern for blood collectors and transfusion service scientists and clinicians. Accordingly, a number of the nation's leading blood safety experts have repeated called for initiation of a program to detect the presence of bacteria in blood and blood products.

5. In general, development of an effective test for detecting bacterial contamination is a formidable task and is unlike the development of effective tests for various viral agents for two reasons: (1) a bacterial test should detect the presence of the whole organism rather than the donor's immune response because donors may already have antibodies from previous exposures to certain bacteria; and (2) in many instances transfusion associated sepsis involves non-pathogenic environmental bacterial contaminants as opposed to pathogenic contaminants. Furthermore, an ideal test should be able to detect all or most of the diverse bacterial species implicated in transfusion-associated sepsis. *See*, Stephen J. Wagner, (Zentralblatt für Bacteriologie 283(3): 253-257 (1996).

6. In particular, developing immunological-based test is further complicated because it was thought that there were likely to be no exposed common antigens on the surface of all the diverse bacterial species implicated in transfusion associated bacterial sepsis.

7. In fact, at least one company, Binax used an immunological-based approach and failed. Binax in collaboration with the American Red Cross, developed a prototype assay using immunological methods to detect bacterial contamination of blood components. The test was developed to detect the presence of microbial antigens which were exposed after

physical or chemical treatments and subsequently visualized by immunochromatography. However, Binax subsequently abandoned the test due to a limitation in its ability to detect all the bacteria implicated in platelet transfusions at levels below 10^5 CFU/mL.

8. As of 2001, no practical test was available to rapidly and accurately test for clinically relevant amounts of bacteria using antibodies. (Seaver et al. *Transfusion* 41: 1351-1355 (2001)) To the best of my knowledge no such reliable test is currently on the market.

9. To date, to the best of my knowledge, despite experimental measures to sterilize the collection of blood, transfusion-associated bacterial sepsis continues to be a concern in transfusion medicine. Further, despite many attempts, no detection technique has been implemented that meets all the requirements for a successful rapid test to be used just prior to transfusion.

10. Due to the failure of other immunoassays to detect bacteria in blood with adequate sensitivity, investigators in the field of blood banking have questioned whether an immunoassay, such as the one described and claimed by Verax would be successful.

11. I believe that the assay developed by Verax may provide the blood banking industry with a long-awaited method to rapidly and effectively test for clinically relevant amounts of bacterial contaminants in blood, blood products, and tissues collected at donation centers. Because they have been able to detect clinically relevant levels of diverse species of organisms using their two antibody system where others have failed, I believe that the Verax test provides a non-obvious solution to meet this need in the blood banking arena.

12. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

Dated: 12/11/03 Signature: Stephen J. Wagner

Stephen J. Wagner
Title: Director of Cell Therapy
Holland Laboratory of the American Red Cross

12/11/03

STEPHEN J. WAGNER
American Red Cross Blood Services
Jerome H. Holland Laboratory for the Biomedical Sciences

Education

B.S. Chemistry, University of Maryland, College Park, MD, 1977
M.S. Biophysics, The Pennsylvania State University, University Park, PA, 1979
Ph.D. Biophysics, The Pennsylvania State University, University Park, PA, 1981

Experience

1972-1977	Technician, Chemistry Dept., Univ. MD, College Park, MD
1977	Technician, Jet Propulsion Lab., Pasadena, CA
1977-1981	Teaching Assistant, Dept. of Biophysics, The Penn. State Univ., Univ. Park, PA
1977-1981	Research Assistant, Dept of Biophysics, The Penn. State Univ., Univ. Park, PA
1981-1982	Postdoctoral Fellow, Laboratory of Genetics and Recombinant DNA NCI-Frederick Cancer Research Facility, Frederick, MD
1982-1986	R & D Scientist, Zetachron Inc., State College, PA
1986-1989	Postdoctoral Scholar, Dept. of Molecular and Cell Biology, The Penn. State Univ. Univ. Park, PA
1989-1992	Scientist I, Product Development Department, American Red Cross, Holland Laboratory for the Biomedical Sciences, Rockville, MD
1992- 1997	Scientist II, Product Development Department, American Red Cross, Holland Laboratory for the Biomedical Sciences, Rockville, MD
1997-2002	Senior Scientist, Product Development Department, American Red Cross, Holland Laboratory for the Biomedical Sciences, Rockville, MD
2002-present	Director Cell Therapy Development, Blood & Cell Therapy Development American Red Cross, Holland Laboratory for the Biomedical Sciences, Rockville, MD

Honors, Awards, Professional Recognition

Cum Laude, University of Maryland, College Park, 1977
Phi Kappa Phi
Alpha Chi Sigma Award, 1977, Univ. of MD; awarded to an outstanding senior graduating in chemistry
The Daymon Runyon-Walter Winchell Fellowship Grant, 1982, NCI FCRC, Frederick, MD
National Tiffany Award, 1997, from the American Red Cross for outstanding technical achievement
Appointed to the editorial board of **TRANSFUSION** (2001-2003)
Member of AABB Transfusion-Transmitted Diseases Committee (2001-present)
Scientific Advisor to FDA Bacterial Contamination Working Group (2001-present)
Ad Hoc Reviewer for SPIR and STTR Grants, Transfusion Medicine (2001-present)
Member of the American Red Cross National IRB (1999-present)
Member of the American Red Cross Patent Disclosure Committee (2001-present)

Grant Awards
1994-1997, NIH NHLBI, HL-94-05-B, "Novel Photoactive Virucides for Red Cells and Platelets, Total Direct Costs $700,526

2001-2005, NIH NHLBI, HL66779, "Virus photoinactivation – Dimethylmethylene blue in RBC, Total Direct Costs $1,250,000

Professional Society Memberships
American Society for Microbiology
American Society for Photobiology
American Association of Blood Banks
International Society for Blood Transfusion
American Society for Hematology

Academic appointment
Adjunct Associate Professor, Bowling Green State University, 1993, research advisor to Jean T. Scherrer: Master of Science thesis: Comparison of bacterial growth in platelet concentrates prepared by the platelet-rich plasma and the buffy coat methods.

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Wagner SJ, Myrup A, Celluzzi C: Method for enriching adherent monocyte populations, in prosecution.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GOODNOW

Serial No: 09/616,283

Filed: July 14, 2000

For: SYSTEM FOR DETECTING BACTERIA IN BLOOD, BLOOD PRODUCTS, AND FLUIDS OF TISSUES

Art Unit: 1645

Attorney Docket No. VRXB-P01-001

Examiner: J. Hines

Assistant Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration Under 37 C.F.R. §1.132

Sir:

I, Jeffrey A. Hall, Ph.D., of Franklin, MA, hereby declare as follows:

1. I am the Director of Assay Development at Verax Biomedical, Inc., the assignee of the present application. I have been conducting research in immunoassay development for 13 years. Accordingly, my curriculum vitae is attached as Appendix A.

2. I have read the above-identified application, the pending claims, the Office Action mailed on February 11, 2003 and the Office action mailed on September 29, 2003.

3. I understand that the Examiner has stated that the invention as described and claimed in the above-identified application is obvious in view of the teachings of Fisher et al. WO 98/57994, McLaughlin (U.S. Patent 4,683,196), Tadler et al. (*J. Clin. Lab. Anal.* 3: 21-25 (1989)), Erich et al. (*J. Immunol.* 143(12): 4053-4060, 1989), and Chang et al. (U.S. Patent 5,200,323).

4. The Examiner states that McLaughlin teaches antibodies which specifically bind to gram negative bacteria in order to determine their presence and/or absence while Tadler et al., teach well known binding agents that bind lipotechoic acid of gram-positive bacteria in assays. See Office Action dated February 11, 2003. In the current Office Action the Examiner admits that the McLaughlin antibodies are not pan-generic but states that it would have been to obvious modify the assay to include the antibodies taught by Erich et al. instead of the McLaughlin antibodies. Similarly, Examiner admits that the Tadler et al. antibodies are not pan-generic but states that it would have been obvious to modify the assay to include the antibodies taught by Fischer et al. instead of the Tadler et al. antibodies.

5. I have reviewed the disclosures of all the cited references: McLaughlin, Erich et al., Tadler et al., and Fischer et al. For the reasons set forth below and the accompanying experimental data, I believe that the prior art antibodies fail to demonstrate broad pan-generic cross-reactivity and detection at a level of sensitivity to be effective in detecting clinically relevant amounts of bacteria in a blood or blood products as required by the claims.

6. Verax Biomedical, Inc., has developed pan-generic antibodies immunoreactive with the Gram-negative antigen lipopolysaccharide (LPS) and pan-generic antibodies immunoreactive with the Gram-positive antigen lipoteichoic acid (LTA). The pan-generic activity and sensitivity of these antibodies has been compared with the closest commercially available antibodies that are being marketed for pan-generic reactivity. We

set forth below the comparative results obtained for the Verax gram positive as well as the gram negative antibodies.

Gram-Positive Antibodies

7. The Examiner states that Tadler et al disclose well known binding agents that bind the lipoteichoic acid (LTA) of the Gram-positive bacteria. We purchased commercially available antibodies that bind the LTA of the Gram-positive bacteria [Appendix B] and performed a side-by-side comparison with the Verax antibodies (VERAX PGD BA-3).[1]

8. The specification as filed discloses how to make and use pan-generic gram positive antibodies. Example 9 of the application demonstrates to one of ordinary skill in the art that the Verax monoclonal antibody clone 96-110 (described in WO 98/57994 by Fisher et al.; now designated as Verax PGD BA-3) shows pan-generic reactivity with seven Gram-positive bacteria as depicted in Figure 5 of the application. [Appendix C].

9. In addition, to the examples described in Example 9, we have generated and screened for additional antibodies that are pan-generic in nature and are capable of detecting clinically relevant amounts of bacteria using the methods taught in the specification at pages 24-26. VERAX PGD BA-4 is an example of such an antibody.

10. We conducted further assays comparing the Verax antibodies, such as VERAX PGD BA-3 and VERAX PGD BA-4 to commercially available antibodies from HyCult Biotech and Biogenesis, Inc. We evaluated the ability of these antibodies to detect clinically

[1] The VERAX PGD BA-3 antibody is the same as the antibody described in Example 9, i.e., the Fischer antibody of clone 96-110.

relevant amounts of bacteria and to be useful in constructing meaningful screening assays. These results are presented below:

PAN-GENERA REACTIVITIES (S:N RATIO) OF VARIOUS BINDING AGENTS TOWARDS GRAM POSITIVE BACTERIA

		TEST BACTERIA								
Vendor	Antigen	Staph epidermidis	Staphylococcus aureus	Staph lugdenensis	Bacillus subtilis	Group B Streptococcus	Group G Streptococcus	Enterococcus faecalis	Corynebacterium sps	Clostridium perfringes
HyCult Biotech	G+ LTA	28.1	1.2	1.4	1.3	1.5	3.8	1.9	3.8	1.7
Biogenesis Inc.	G+ LTA	9.2	16.3	1.1	2.9	1.5	6.7	1.3	6.7	2.2
VERAX PGD BA-3	G+ LTA	62.6	7.6	12.5	20.3	5.6	14.8	5.8	14.8	4.7
VERAX PGD BA-4	G+ LTA	77.9	30.1	71.3	10.2	6.6	10.8	21.4	10.7	2.8

* "SAMPLE-TO-NOISE" RATIO = ANTIGEN-SPECIFIC SIGNAL/BACK-GROUND SIGNAL

** S:N RATIO IS A COMMON EIA DATA NORMALIZATION TECHNIQUE TO SIMULTANEOUSLY COMPARE REACTIVITIES OF MULTIPLE BINDING AGENTS. A S:N RATIO >2 IS REQUIRED TO CONSTRUCT A MEANINGFUL ASSAY.

Our results show that the commercially available antibodies were not truly pan-generic with respect to the detection of the LTA on Gram-positive bacterium and would not be useful in constructing a meaningful blood screening assay. In contrast, the Verax antibodies detected seven genera of Gram-positive bacterium routinely found in contaminated blood. See results above and Figure 5.

11. To be effective, a signal: noise ratio greater than two (2) is required for constructing a meaningful assay. The commercially available antibodies failed to demonstrate a ratio greater than two. As can be seen from the Table above, the Hycult Biotech antibody

failed to detect two species of *Staphylococcus* bacterium, *Bacilis subtilis*, Group B *Streptococcus*, *Enterococcus*, *Corynebacterium*, and *Clostridium*. Similarly, the Biogenesis Inc. antibody failed to detect one species of *Staphylococcus* bacterium, Group B *Streptococcus and Enterococcus*. In contrast, the Verax antibodies were effective in detecting seven different genera of bacteria and the signal was considerably stronger than that observed for the commercially available antibodies.

12. We now provide a side-by-side comparison of the pan-generic reactivity of the Verax antibodies to the Tadler et al. antibodies. Tadler et al. discloses an immunoassay for the detection of the LTA on gram positive bacteria. A close review of their experimental data shows that their antibodies demonstrate limited binding and detection of four bacterial genera: *Streptococcus spp.*, *Staphylococcus spp.*, *Enterococcal spp.*, and *Clostridium*. In contrast, the Verax antibodies are capable of pan-generic binding and detection of at least seven Gram-positive bacterial genera.

13. We further provide a comparison of the sensitivity of the Verax antibodies to the Tadler et al. antibodies. Figure 2 of Tadler et al. shows that only 2 bacterial genera, i.e., *Streptococcus mutans* and *Staphylococcus epidermidis*, are detected at clinically relevant amounts, $5x10^5$ CFU/50µl (i.e., $1x10^7$ CFU/ml). Thus, at this level of sensitivity the Tadler antibodies are not truly pan-generic. The bacteria *Staphylococcus aureus* is detected at $5x10^6$ CFU/50µl (i.e., $1x10^8$ CFU/ml), a level that is not clinically relevant. Additionally, the Tadler et al. immunoassay was unable to detect *Staphylococcus faecuim* at $5x10^6$ CFU/50µl ($1x10^8$ CFU/ml) suggesting that the antibodies are only able to cross-react with LTA on certain Staphylococcus *spp.* and Streptococcus *spp.* Therefore, in

effect, Tadler et al. show detection of only two genera of gram-positive bacteria at clinically relevant amounts as is required by the claims. See Figure 2 of Tadler et al.

14. In contrast, the following Table set forth both the pan-generic cross-reactivity of the Verax antibodies, as well as the sensitivity of these antibodies, demonstrating a greater degree of sensitivity in detecting clinically relevant amounts of bacteria in contaminated blood or blood products ($1x10^2$ CFU/ml – $1x10^6$ CFU/ml).

	GRAM POSITIVE RAPID TEST SIGNAL (G/DENS)										
CFU/ml	*S. epidermidis*	*S. aureus*	*S. lugdenensis*	*B. cereus*	GRP B Strep	GRP G Strep	*S. pyogenes*	*E. faecalis*	*C. minutissimum*	*C. perfringes*	CFU/ml
1.0 E5	17.26	1.04	13.21	12.24	0.26	16.07	nt	13.95	6.82	11.20	**1.0 E5**
5.0 E4	nt	nt	3.20	9.91	nt	nt	21.77	nt	nt	nt	**5.0 E4**
1.0 E4	8.81	0.41	0.36	2.45	0.04	1.43	10.32	3.19	2.03	8.67	**1.0 E4**
5.0 E3	3.98	nt	nt	nt	0.04	nt	nt	0.44	nt	nt	**5.0 E3**
1.0 E3	0.83	0.24	0.17	0.29	nt	0.46	0.51	0.27	1.26	2.91	**1.0 E3**

*BOXED CELL = MINIMALL DETECTABLE CONCENTRATION
**G/DENS = REFLECTANCE SIGNAL, ANY G/DENS > 0.25 IS VISIBLE
***nt = NOT TESTED

15. We now examine the pan-generic cross-reactivity of the Fischer et al antibody as taught by the Fischer PCT publication . The Fischer PCT publication referenced by the Examiner fails to disclose or suggest pan-generic activity. The Table below provides a comparison of the properties shown in the Fischer references in comparison to the properties of the Fischer antibody now appreciated and recognized by Verax.

Gram positive bacterial species recognized by the Fisher antibody as taught by the Fischer reference	Gram positive bacterial species recognized by the Fisher antibody as taught by the instant application

Staphylococcus spp.	*Staphylococcus spp.* *Streptococcus pyogenes* *Group B Streptococcus* *Group G Streptococcus* *Enterococcus faecalis* *Corynebacterium minutissimum* *Clostridium perfringens* *Bacillus spp.*

Thus, the Fisher et al. reference shows binding to ***only*** one bacterial genus: the Staphylococcus genus: there was no recognition of its pan-generic ability in the Fischer reference.

Gram-Negative Antibodies

16. The Examiner states that McLaughlin and/or Erich et al. disclose antibodies which specifically bind to gram-negative bacteria. McLaughlin discloses mouse and rabbit antibodies that bind to the Lipid A core of the LPS on Gram-negative bacteria. Erich et al disclose three murine monoclonal antibodies and state that one of the three antibodies showed cross-reactivity with the heterlogous LPS and Gram bacterial strains but cross-reactivity was either moderate or virtually absent for the remaining two. See Page 4058. We conducted a side-by-side comparison of the Verax antibodies to the closest commercially available mouse antibodies that are marketed as being anti-LPS core or anti-endotoxin [Appendix D] from HyCult Biotech, Virostat, and QED.

17. The specification as filed discloses how to make and use pan-generic gram negative antibodies. Example 9 of the application demonstrates to one of ordinary skill in the art

that the Verax monoclonal antibody clone 26-5 (commercially available from Biodesign International) shows pan-generic reactivity with the LPS of seven Gram-negative bacteria as depicted in Figure 6 of the application. [Appendix E].

18. In addition to the examples described in Example 9, we have generated and screened for additional antibodies that are pan-generic in nature and are capable of detecting clinically relevant amounts of bacteria using the methods taught in the specification at pages 24-26. VERAX PGD BA-1 and VERAX PGD BA-1 are examples of such antibodies.

19. McLaughlin antibodies are reactive with gram-negative bacteria such as *Neisseria, Chlamydia, and Salmonella.* The Erich et al antibodies are cross-reactive with only two (live) bacterial genera: *Escherichia* and *Salmonella.* In contrast, the Verax antibodies show pan-generic activity against a range of bacteria that have been identified as contaminants in blood and blood products in three major national transfusion reaction studies including the BaCon Study in the United States, the Hemovigilance study in France, and the SHOT study in the United Kingdom. These contaminants include both pathogenic as well as non-pathogenic bacterial species such as *Yersinia entercolitica* and *Proteous miribilis*, along with other common soil-borne bugs. The McLaughlin and Erich et al antibodies appear to be effective mainly against the pathogenic gram negative bacterial species (e.g., *Neisseria, Escherichia,* and *Chlamydia*).

20. In addition, we conducted further assays using Verax antibodies, in evaluating the ability of these antibodies to detect clinically relevant amounts of bacteria and be useful in constructing meaningful screening assays. These results are presented below:

PAN-GENERA REACTIVITIES (S:N RATIO) OF VARIOUS BINDING AGENTS TOWARDS GRAM NEGATIVE BACTERIA

TEST BACTERIA

Vendor	Antigen	*Enterobacter cloacae*	*Enterobacter aerogenes*	*Acinetobacter baumanii*	*Klebsiella oxytoca*	*Klebsiella pneumoniae*	*Escherichia coli*	*Pseudomonas aeruginosa*	*Salmonella enteritidis*	*Yersinia enterocolitica*	*Proteus mirabilis*	*Serratia marcescens*
HyCult Biotech	LPS	1	1	1.1	1.2	1.1	1.2	1	1	1	1.3	1.3
Virostat	LPS	1	1	1	1	1	1	1	1	1	1	1.1
QED	LPS	1	1	1	1	1	1	NT	NT	NT	NT	NT
VERAX PGD BA-1	LPS	12.1	11.1	12.5	12.8	12.3	9.6	9.7	11.2	11.4	10.6	12.3
VERAX PGD BA-2	LPS	11.2	16.5	14.2	9.5	7.8	13.5	9.2	8.5	12.1	19.5	22.7

* "SAMPLE-TO-NOISE" RATIO = ANTIGEN-SPECIFIC SIGNAL/BACK-GROUND SIGNAL
** S:N RATIO IS A COMMON EIA DATA NORMALIZATION TECHNIQUE TO SIMULTANEOUSLY COMPARE REACTIVITIES OF MULTIPLE BINDING AGENTS
A S:N RATIO >2 IS REQUIRED TO CONSTRUCT A MEANINGFUL ASSAY.

21. To be effective, a signal: noise ratio greater than two (2) is required for constructing a meaningful assay. As can be seen from the Table above, the commercially available antibodies failed to detect all nine bacterial genera. In contrast, the Verax antibodies were effective in detecting nine different genera of bacteria and showed strong signals for each of these bacteria. Thus, the Verax antibodies showed greater effectiveness than the commercially available antibodies.

22. In addition, the following Table sets forth the sensitivity of the Verax gram negative antibodies, demonstrating a greater degree of sensitivity in detecting clinically relevant amounts of bacteria in contaminated blood or blood products ($1x10^2$ CFU/ml – $1x10^6$ CFU/ml).

VERAX PLATELET PGD ASSAY: ANALYTICAL SENSITIVITY

	GRAM NEGATIVE RAPID TEST SIGNAL (G/DENS)										
CFU/ml	*E. coli*	*Ps. aeruginosa*	*E. aerogenes*	*K. oxytoca*	*E. cloacae*	*A. baumanii*	*K. pneumoniae*	*S. enteritidis*	*P. mirabilis*	*S. marcescens*	CFU/ml
1.0 E5	4.51	2.16	9.13	8.66	1.01	7.71	5.30	1.14	1.38	0.83	**1.0 E5**
5.0 E4	4.10	1.45	7.70	7.08	0.77	7.51	4.40	0.70	0.98	0.71	**5.0 E4**
1.0 E4	2.75	0.79	6.88	3.31	0.82	4.79	2.34	0.50	0.56	0.69	**1.0 E4**
5.0 E3	1.34	0.67	4.81	1.46	0.73	2.98	1.21	0.48	0.24	0.16	**5.0 E3**
1.0 E3	0.99	0.32	4.10	0.25	0.75	1.46	0.57	0.04	0.09	0.01	**1.0 E3**

23. For these reasons, I believe that the closest commercially available prior art antibodies do not show the pan-generic activity or sensitivity required to be effective in detecting clinically relevant amounts of bacterial contaminants in blood and blood products.

24. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

Dated: 12/2/03

Signature: _____

Dr. Jeffrey A. Hall, Ph.D
Director, Assay Development
Verax Biomedical Incorporated

CURRICULUM VITAE

Jeffrey A. Hall, Ph.D

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DEGREES:

1986-1988	Doctor of Philosophy (Reproductive Physiology), West Virginia University, Morgantown, West Virginia.
1982-1986	Master of Science (Reproductive Physiology), West Virginia University, Morgantown, West Virginia.
1978-1982	Bachelor of Science (Biological and Agricultural Sciences), Arizona State University, Tempe, Arizona.

WORK EXPERIENCE:

2001-	**Director, Assay Development, Verax Biomedical Inc., Worcester, MA.**
1999 - 2000	**Manager, Industrialization Group - VIDAS Probe, bioMerieux, Inc., Rockland, MA.**
1997 - 1999	**Senior Staff Scientist, Infectious Disease Assay Development, Bayer Diagnostics (formerly Chiron Diagnostics Corp.), E. Walpole, MA.**
1995 -1997	**Staff Scientist, Infectious Disease Assay Development, Chiron Diagnostics Corp. (formerly Ciba-Corning Diagnostics), E. Walpole, MA.**
1994-1995	**Senior Scientist, Assay Development R&D, Dade International (formerly Baxter Diagnostics Inc.)**
1991-1994	**Scientist, Assay Development R&D, Baxter Diagnostics Inc. (Miami, FL)**
1988-1990	**Post-Doctoral Research Associate, Reproductive Physiology Unit, University of Missouri-Columbia (Columbia, MO.)**

HONOR SOCIETIES:

Beta Beta Beta
Gamma Sigma Delta
Phi Kappa Phi
Sigma Xi

AWARDS:

1987 First Place Award, Sigma Xi Graduate Research Colloquium, West Virginia University
1986-88 Swigert Award for Outstanding Doctoral Research Assistant, West Virginia University
1985 Third Place Award, Northeast Section Am. Soc. Animal Science, Graduate Research Competition, West Virginia University

MEMBERSHIPS:

American Association of Blood Bankers
American Association of Clinical Chemistry
American Society of Microbiology
American Association for the Advancement of Science

REFEREED PUBLICATIONS:

Hall, J., W. Jilg, B. Hottentraeger, P. Bonnar, C. Fang, L. Baker. 1998. Performance of a chemiluminescent immunoassay for HBsAg on a new high-throughput and fully automated ACS:Centaur system. Clin. Lab. 44:349-354.

Hall, J.A., R.A. Dailey, P.E. Lewis. 1993. Effect of the corpus luteum of pregnancy on ovulation and luteal function in early post-partum ewes. J. Anim. Sci. 71:3067-3072.

Hall, J.A., B.N. Day, R.V. Anthony. 1993. Influence of steroids on relaxin-induced changes in distensibility and composition of the cervix in gilts. Biol. Reprod. 48:1348-1353.

Hall, J.A., E.M. Meisterling, A.M. Benoit, D.A. Cooper, D.A. Coleman, S.P. Lerner, P.E. Lewis, R.A. Dailey. 1993. Factors contributing to the formation of experimentally-induced ovarian cysts in prepubertal gilts. Dom. Anim. Endocrinol. 102:141-155.

Hall, J.A., T.C. Cantley, J.M. Galvin, B.N. Day, R.V. Anthony. 1992. Influence of ovarian steroids on relaxin-induced uterine growth in ovariectomized gilts. Endocrinol. 130:3159-3160.

Trout, W.E., J.A. Hall, M.L. Stallings-Mann, J.M. Galvin, R.V. Anthony, R.M. Roberts. 1992. Steroid regulation of the synthesis and secretion of retinol-binding protein by the uterus of the pig. Endocrinol. 130:2557-2564.

Caldwell, R.W., R.A. Bellows, J.A. Hall, R.V. Anthony. 1990. Administration of porcine relaxin to beef heifers four or seven days prepartum. J. Reprod. Fertil.

Hall, J.A., T.C. Cantley, B.N. Day, R.V. Anthony. 1990. Uterotropic actions fo relaxin in prepubertal gilts. Biol. Reprod. 42:769-774.

Weems, C.W., Y.S. Weems, J. Hall, B. DeGroot, C.N. Lee, D.L. Vincent. 1989. Effects of chronic infucion of dibutyryl-cAMP or adenosine on luteal function in sheep. Endocrinol. Japon. 36:439-447.

Hall, J.A., E.M. Meisterling, P.E. Lewis, R.A. Dailey. 1989. Formation of ovarian cysts and copora lutea after treatment with anti-histamine or indomethacin in prepubertal gilts. Biol. Reprod. 40:565-569.

NON-REFEREED PUBLICATIONS:

Moll, F., S. Lin, J. Hall. 1994 (June). Dendrimers: An enhancement of core technology for Stratus assays. In: *Tabline*, Technical Bulletin for Stratus Immunochemistry Analyzer.

Hall, J. 1994 (August). Dendrimer Technology: Expanded flexibility of assay format capabilities for Stratus instrumentation. In: *Tabline*, Technical Bulletin for Stratus Immunochemistry Analyzer.

Caldwell, R.W., R.A. Bellows, J.A. Hall, R.V. Anthony. 1990. Administration of porcine relaxin to beef heifers four or seven days prepartum. In: 1989 Missouri Beef Cattle Report, Univ. Missouri.

Dailey, R.A., J.A. Hall, E.M. Meisterling. 1987. What causes ovarian cysts? In: Inquiry- 1987, West Virginia University Annual Research Report.

SELECTED ABSTRACTS:

Bonnar, P., M. Vasily-Cioffi, C. Chiodini, J. Bonapace, L. Baker, J. Hall. 1999. Development of a chemiluminescent assay for detection of toxoplasma IgG. Annual Meeting Amer. Soc. Micro.

Sliwinski, G., S. Bonapace, J. Green, F. Kenny, L. Baker, J. Hall. 1999. Development of a chemiluminescent assay for detection of toxoplasma IgM. Annual Meeting Amer. Soc. Micro.

Hall, J., P. Bonnar, G. Sliwinski, L. Baker. 1999. Development of toxoplasma serology assays for the ACS:Centaur. Annual Meeting Int. Fed. Clin. Chem.

Hall, J., G. Sliwinski, M. Lynch, L. Baker. 1998. An automated chemiluminescent immunoassay system for quantitative determination of specific antibodies to hepatitis B surface antigen. Annual Meeting Oak Ridge Conference.

Sliwinski, G., B. Rojik, D. Deslauriers, L. Baker, J. Hall. 1998. Development of a quantitative anti-HBs chemiluminescent assay for the ACS:Centaur immunoassay analyzer. Annual Meeting Amer. Soc. Microbiol.

Kenny, F., A. Saadat, T. Reidy, L. Baker, J. Hall. 1998. Development of an anti-HBc (IgM) chemiluminescent assay for the ACS:Centaur immunoassay analyzer. Annual Meeting Amer. Soc. Microbiol.

Hall, J., K. Broadwell, A. McKinnon, D. Masi, D. Bedard, L. Baker. 1998. Development of a hepatitis B surface antigen (HBsAg) chemiluminescent assay for the ACS:Centaur immunoassay analyzer. Annual Meeting Amer. Soc. Microbiol.

Bonnar, P., M. Cioffi, P. Wunderli, L. Baker, J. Hall. 1998. Development of a confirmatory chmiluminescent assay for hepatitis B surface antigen (HBsAg) for the ACS:Centaur. Annual Meeting Amer. Soc. Microbiol.

Wunderli, P., R. Drolet, L. Peters, T. Reidy, N. Masillo, M. Jackson, L. Baker, J. Hall. 1998. Development of an anti-HBc (total) chemiluminescent assay for the ACS:Centaur immunoassay analyzer. Annual Meeting Amer. Soc. Microbiol.

Hall, J., P. Bonnar, F. Kenny, G. Sliwinski, P. Wunderli, L. Baker. 1998. Performance of chemiluminescent immunoassays for HBV markers on the automated ACS:Centaur system. Annual Meeting Amer. Assoc. Clin. Chem.

Gammie, A., S.A. Ball, G. Sliwinski, L. Baker, C. Fang, J. Hall. 1998. Reliable quantitative measurement of anti-HBs by an automated chemiluminescent immunoassay system. Annual Meeting UK Virol. Symp.

Hall, J., G. Sliwinski, J. Green, S. Bonapace, J. Bonapace, L. Baker. 1998. HBsAg functionality affects the quantitative measurment of anti-HBs. Annual Meeting Eur. Soc. Clin. Virol.

Wunderli, P., F. Kenny, R. Drolet, L. Peters, L. Baker, J. Hall. 1998. Importance of IgM detection in early seroconversion sensitivity of total anti-HBc assays. Annual Meeting Eur. Soc. Clin. Virol.

Sliwinski, G., K. Vellieux, H. Kirchick, J. Hall. 1996. Development of chemiluminescent IgM anti-HBc assay for ACS instrumentation. Annual Meeting Amer. Soc. Microbiol.

Hall, J.A., J. Cobb, F. Moll, K. Yu, J. Conde, S. Lin, P. Singh, R. Bauer. 1994. CK-MB assay performance for Stratus instrumentation using dendrimer technology. Annual Meeting Amer. Assoc. Clin. Chem.

Hall, J.A., A.D. Okonmah, D.J. Stade, F. Boches, H.J. Kirchick. 1992. Development of IgG class capture for Stratus radial partitioning enzyme-immunoassay (RPEIA) technology. Annual Meeting Amer. Assoc. Clin. Chem.

Hall, J.A., T.C. Cantley, J.M. Galvin, B.N. Day, R.V. Anthony. 1991. Influence of relaxin on ovarian steroid-induced uterine growth in ovariectomized gilts. Annual Meeting Endocrin. Soc.

Hall, J.A., B.N. Day, R.V. Anthony. 1991. Influence of steroids on relaxin-induced changes in distensibility and composition of the cervix in gilts. Biol. Reprod. (Supp. 1) 44:446.

Trout, W.E., J.A. Hall, R.V. Anthony. 1991. Uterine retinol-binding proteins of the pig: expression during pregnancy and induction by conceptus estrogen. Biol. Reprod. (Supp. 1) 44:363.

Hall, J.A., T.C. Cantley, B.N. Day, R.V. Anthony. 1989. Uterotropic actions of relaxin in prepubertal gilts. Biol. reprod. (Supp. 1) 40:453.

Cooper, D.A., J.A. Hall, E.K. Inskeep, R.A. dailey. 1988. Functional characterisitics of induced ovarian cysts in prepubertal gilts. J. Anim. Sci. (Supp. 1) 66:518.

Hall, J.A., E.M. Meisterling, R.A. Dailey. 1987. Effect of indomethacin on cyst formation and ovulation in prepubertal gilts. Biol. Reprod. (Supp. 1) 36:95.

Hall, J.A., R.A. Dailey, E.K. Inskeep, P.E. Lewis. 1987. Effect of the corpus luteum of pregnancy on ovulation and luteal function in early post-partum ewes. J. Anim. Sci. (Supp. 1) 65:61.

Hall, J.A., E.M. Meisterling, R.A. Dailey. 1986. Effect of H1 and H2 receptor antagonists on cyst formation in prepubertal gilts. J. Anim. Sci. (Supp. 1) 63:361.

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Keisler, D.H., J.A. Hall, P.E. Lewis. 1983. The effect of ovariectomy on preovulatory surge of LH induced by pulsatile delivery of LH into prepubertal ewe lambs. Biol. Reprod. (Supp. 1) 28:95.

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0100-0037	Lipoteichoic Acid (LTA)	200 µg	£155 $269 €282
	antibody, mouse clone BGN/11/40?? (IgG3): purified, ELISA 1/5000 (50%B) ELISA >1/250K (EPT)		

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↳ HY-CULT BIOTECH (THE NETHERLANDS)

HM2090 *NEW*	Mouse monoclonal antibody against Human L-Ficolin, Clone GN4	IA, IP, W	100 µg
HM2091 *NEW*	Mouse monoclonal antibody against Human L-Ficolin, Clone GN5	IA, IP, W	100 µg

*T

LPS, MICROBIAL TOXINS AND RELATED PROTEINS:

Cat. no.	Product	Applications	Quantity
HM2045	Mouse monoclonal antibody against KDO, Clone 20	IA, W	>200 µg/ml 1 ml supernatant
HM2046	Mouse monoclonal antibody against free Lipid A, Clone 43	IA, W	>200 µg/ml 1 ml supernatant
HM2048	Mouse monoclonal antibody against Lipoteichic Acid (LTA), Clone 55	IA, W	>200 µg/ml 1 ml supernatant
HM6001	Mouse monoclonal antibody against LPS core, Clone WN1 222-5	B, IA, P, W	100 µg
HM2047	Mouse monoclonal antibody against Polymyxin B (PMB), Clone 45	IA, W	>200 µg/ml 1 ml supernatant
HC4020	Polymyxin B (PMB)	B, IA	10^5 units
HC4021	Polymyxin B (PMB), biotinylated	IA	0.2 ml
HC4022	Polymyxin B (PMB), HRP conjugated	IA	0.2 ml
HM6002	Mouse monoclonal antibody against TSST-1, Clone Mab5	B, IA, W	100 µg
HK506 *NEW*	TSST-1 ELISA	IA	Under development

*T

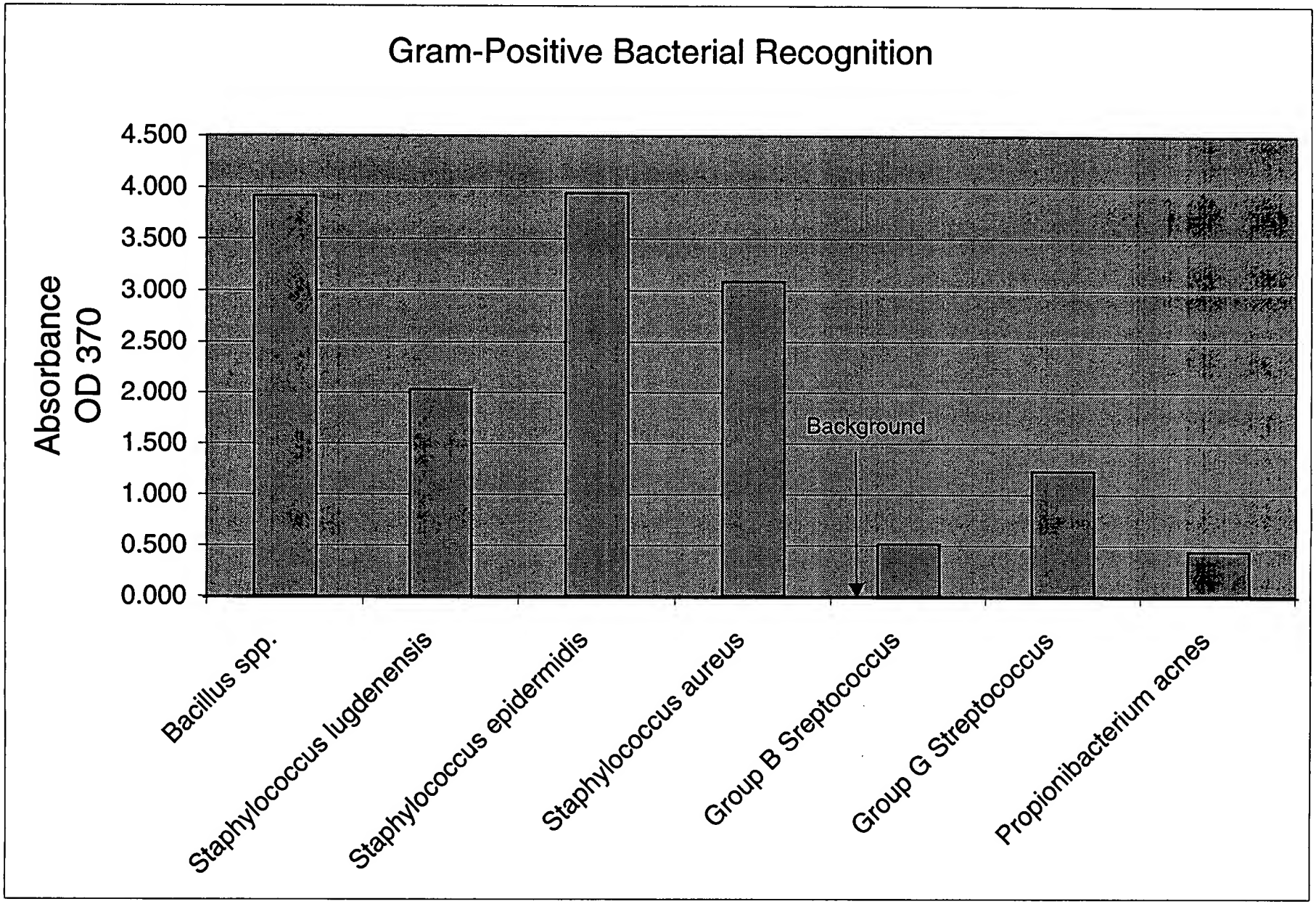
SAA (Serum Amyloid A)

Cat. no.	Product	Applications	Quantity
HM2100 *NEW*	Mouse monoclonal antibody against Human SAA Clone Reu86.1	F, IA, P	100 µg
HM2101 *NEW*	Mouse monoclonal antibody against Human SAA Clone Reu86.5	F, IA, P	100 µg

*TOP

SLPI (Secretory Leucocyte Protease Inhibitor):
Secretory leucocyte protease inhibitor (SLPI; also known as antileukoprotease or ALP) is a 11.7 kDa cati inhibitor of neutrophil elastase and to a lesser extent of cathepsin G. It is produced by epithelial cells in tl lung, skin and other organs and by PMN and (in mice) by macrophages.
In addition to its protease inhibitory properties that may serve to protect against proteolytic injury, it was

Figure 5


Gram-Positive Bacterial Recognition
Absorbance OD 370
4.500
4.000
3.500
3.000
2.500
2.000
1.500
1.000
0.500
0.000
Background
Bacillus spp.
Staphylococcus lugdenensis
Staphylococcus epidermidis
Staphylococcus aureus
Group B Sreptococcus
Group G Streptococcus
Propionibacterium acnes

E. coli K99 pili (LP)
#18401-18404
(4 clones)

Price: $235/mg or $235/ml
Host: Mouse

These monoclonal antibodies recognize *E. coli* K99 pili and do not cross-react with K99-negative *E. coli*, *E. coli* K88ac, *E. coli* 987P, *Proteus mirabilis*, *Proteus vulgaris*, *Pseudomonas aeruginosa*, *Enterobacter aerogenes*, *Citrobacter freundii*, or *Klebsiella pneumoniae*. These antibodies may be used in immunoassays to identify K99-positive *E. coli*. Available as ascites, purified antibody, and in a Library Pack.

Endotoxin (LP)
#15301-15309
(9 clones)

Price: $235/mg or $235/ml
Host: Mouse

These monoclonal antibodies recognize endotoxin produced by gram-negative bacteria. Clones differ in degrees of cross-reactivity with a panel of gram-negative endotoxins including *E. coli*, *Klebsiella pneumoniae*, *Shigella sonnei*, *Salmonella typhimurium*, *Enterobacter aerogenes*, *Serratia marcescens*, *Proteus mirabilis*, *Proteus vulgaris*, *Acinetobacter calcoaceticus*, and *Pseudomonas aeruginosa*. Available as ascites, purified antibody, and in a Library Pack.

Entamoeba histolytica (LP)
#15000,15001, 15010, 15020, 15030
(5 clones)

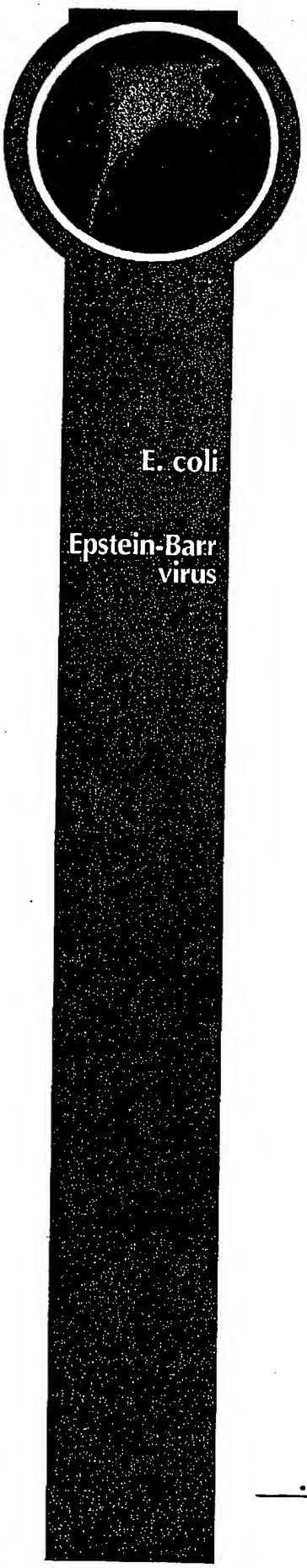
Price: $235/mg or $235/ml
Host: Mouse

These monoclonal antibodies recognize *Entamoeba histolytica* trophozoites and cysts. These antibodies may be used in immunoassays to detect *E. histolytica*. Available as ascites, purified antibody, and in a Library Pack.

Eotaxin
#1123

Price: $210/100 ug
Host: Rabbit

This antibody recognizes human eotaxin, an eosinophil chemoattractant. The eotaxin receptor CCR3 is required for HIV-1 entry into target cells, and eotaxin inhibits infection by HIV-1. A monomer band of 9 kD and a homodimer band of 18 kD are detected in immunoblots. The epitope for this antibody is in amino acids 83-97 of human eotaxin.



MONOTOPE™

(Mouse)
Monoclonal Antibodies*

Continued from previous page

AGENT	SPECIFICITY	PURIFIED (100 UG)	FITC CONJ. (100 UG)
Dengue virus	group	5161 $130	
Diphtheria toxin	—	7801 $130	
Diphtheria toxin	A subunit	7811 $130	
E. coli	common	1011 $130	
E. coli	O157	1031 $145	1033 $170
E. coli	O157	1041 $145	
E. coli	O157	1051 $160	
E. coli	K99	6911 $160	
> Endotoxin	gram neg.	6901 $160	
Enterobacteriaceae	common	1121 $130	
Epstein-Barr virus	EBNA-1	0211 $130	
Epstein-Barr virus	EBNA-1	0216 $130	
Epstein-Barr virus	gp 250/350	0221 $130	0223 $165
Epstein-Barr virus	VCA	0231 $130	
Epstein-Barr virus	VCA-gp	0241 $130	
Epstein-Barr virus	EA-R	0251 $130	
Epstein-Barr virus	EA-D	0261 $130	
Feline Calicivirus	—	7401 $130	
Feline Calicivirus	—	7402 $130	
Feline Immunodeficiency virus	FIV p24	7301 $130	
Feline Immunodeficiency virus	FIV p24	7304 $130	
Feline Immunodeficiency virus	protease	7305 $130	
Feline Immunodeficiency virus	FIV p24	7306 $130	
Feline Immunodeficiency virus	FIV p24	7307 $130	
Feline Immunodeficiency virus	FIV envelope	7312 $130	
Feline Inf. Peritonitis virus	Coronavirus	7321 $130	
Feline Leukemia virus	FeLv p27	7201 $130	
Feline Leukemia virus	FeLv gp70	7202 $130	
Feline Leukemia virus	FeLv gp70	7203 $130	
Feline Leukemia virus	FeLv gp70	7204 $130	
Feline Leukemia virus	FeLv gp70	7205 $130	
Feline Leukemia virus	FeLv gp70	7206 $130	
Feline Leukemia virus	FeLv gp70	7207 $130	
Feline Leukemia virus	FeLv gp70	7208 $130	
Feline Leukemia virus	FeLv gp70	7209 $130	
Feline Leukemia virus	FeLv p15e	7210 $130	
Feline Leukemia virus	FeLv p15e	7211 $130	
Feline Leukemia virus	FeLv p15e	7212 $130	
Feline Leukemia virus	FeLv p15e	7213 $130	
Feline Leukemia virus	FeLv p15e	7214 $130	
Feline Leukemia virus	FeLv p15e	7215 $130	
Feline Rhinotracheitis virus	—	7531 $130	
Giardia lamblia	trophozoites	6211 $130	
Helicobacter pylori	—	6611 $130	

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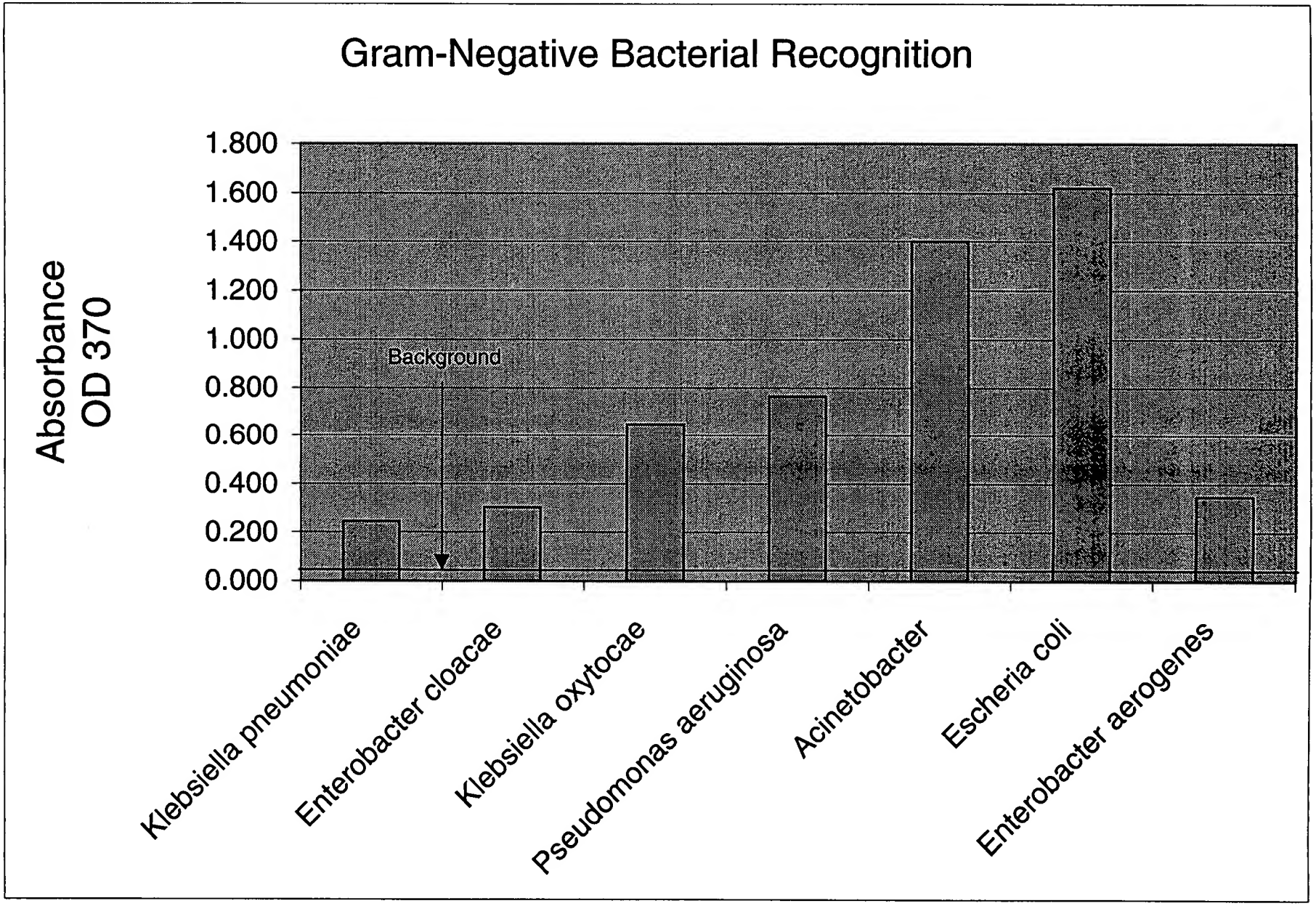
Figure 6


Gram-Negative Bacterial Recognition
Absorbance OD 370
1.800
1.600
1.400
1.200
1.000
0.800
0.600
0.400
0.200
0.000
Background
Klebsiella pneumoniae
Enterobacter cloacae
Klebsiella oxytocae
Pseudomonas aeruginosa
Acinetobacter
Escheria coli
Enterobacter aerogenes